

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations



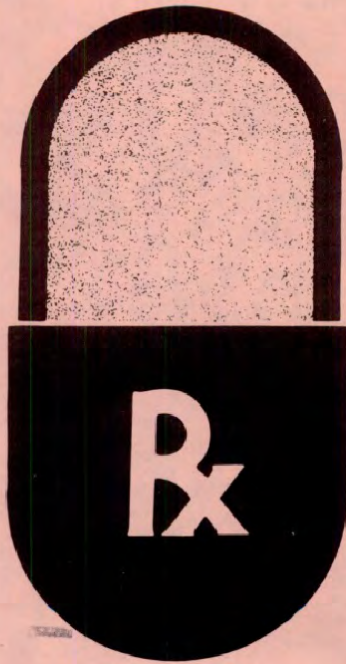
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**CUMULATIVE
SUPPLEMENT 9**
AUG'84 - MAY'85

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5th ed.
Suppl. 9



APPROVED PRESCRIPTION DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

5TH EDITION

SERIAL

REFERENCE

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FOOD AND DRUG ADMINISTRATION
APPROVED PRESCRIPTION DRUG PRODUCTS
WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS
CUMULATIVE SUPPLEMENT

I. PREFACE

This cumulative supplement is one of a series of monthly updates to the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 5th Edition (the List), to cover interim revisions to the annual publication of the List in its entirety. The List is comprised of several parts and some by their nature, are identified by the term "List." The cumulative supplements routinely provide updates to two of these Lists: The Drug Product List and the DESI Addendum.

The List cannot be used effectively without the current cumulative supplement. Users may wish to place an asterisk (*) in the List to the left of the ingredient(s) in the Drug Product List and the product name in the Addendum to indicate that changes to that entry appear in the cumulative supplement. It is also suggested that earlier cumulative supplements be discarded to avoid possible confusion. In this way, only the List and current cumulative supplement need be referenced.

A. DRUG PRODUCT LIST

The Drug Product List cumulative supplements include the changes made since August 1, 1984. Each subsequent cumulative supplement replaces the previous month's cumulative supplement.

Information in this cumulative supplement follows the format of the Drug Product List. The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Context information on drug products is provided in each cumulative supplement for completeness to assist in locating the proper place in the Drug Product List for the revision. (Strength(s) which already exist in the publication will not be repeated for context.) A page number in parentheses referring to the Drug Product List is located to the right of the ingredient(s).

Additions to the Drug Product List are indicated by new information in the cumulative supplement. Additions new to the current cumulative supplement are indicated by the symbol ">Add>" to the left of the line on which new information exists. The ">Add>" symbol is dropped in subsequent cumulative supplements for that item.

Deletions from the Drug Product List are indicated by overstruck print in the cumulative supplement. Deletions new to the current cumulative supplement are indicated by the symbol >DLI> (DELETE) to the left of the line containing the overstruck print. The >DLI> symbol is dropped in subsequent cumulative supplements for that item.

A newly approved product is identified by the lozenge (■) to the right of its strength. This identifier remains throughout all cumulative supplements for this edition.

B. ADDENDUM: DESI Pending List

Information in this cumulative supplement follows the format of the Addendum. Additions and deletions are indicated in the same manner as in the cumulative supplement to the Drug Product List. A change in Current Status of a DESI product is also indicated by an addition and a deletion.

II. SPECIAL NOTES

A. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

Categories of counts derived from product information in the Drug Product List and from this cumulative supplement are presented. The report includes counts of new molecular entities approved by the agency during the current month.

B. PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the Drug Product List.

Products

Federal Register Reference

dicyclomine hydrochloride
isosorbide dinitrate
nandrolone decanoate

JUN 22, 1984 (49 FR 25681)
AUG 3, 1984 (49 FR 31151)
JUL 15, 1983 (48 FR 32395)

(continued)

Products

Federal Register Reference

(continued)

neomycin sulfate with either: dexamethasone sodium phosphate, fluocinolone acetonide, flurandrenolide, hydrocortisone, or methylprednisolone acetate. [topical anti-infectives for dermatologic use]	MAR 26, 1984 (49 FR 11888)
neomycin sulfate, polymyxin B sulfate, bacitracin zinc, and hydrocortisone [topical ointment]	MAY 4, 1984 (49 FR 19147)
nitroglycerin (capsule, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
parenteral multivitamin products	SEP 17, 1984 (49 FR 36446)
phenazopyridine hydrochloride and sulfamethoxazole	JUL 29, 1983 (48 FR 34516)
sulfanilamide and aminacrine	AUG 22, 1983 (48 FR 38097)
tranylcypromine sulfate	MAR 22, 1984 (49 FR 10708)

C. APPLICANT (NAME) CHANGES

Because it is not practical to identify in the cumulative supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name, the cumulation of these transfers and name changes will be identified in this Special Notes section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the cumulative supplement. The current list of applicant holder changes follows.

APPLICANT (NAME) CHANGES

<u>Former Applicant (Name)</u>	<u>New Applicant (Name)</u>	<u>New Abbreviated Name</u>
OHIO MEDICAL ANESTHETICS	ANAQUEST	ANAQUEST

D. ADDENDUM: DRUG PRICE COMPETITION AND PATENT TERM RESTORATION

The addendum of this supplement provides information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984."

E. DISCONTINUED APPROVED PRODUCT IDENTIFIER ("a")

The Drug Price Competition and Patent Term Restoration Act of 1984 requires the FDA to make publicly available an alphabetical list of approved drug products, with the application number and approval date, for each product approved January 1, 1982 and thereafter, and an indication whether in vitro and/or in vivo bioequivalence studies are required for ANDA approval. This publication, Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 5th Edition, and its monthly supplements is being used to satisfy this new requirement. The Agency will no longer delete products from this publication when an applicant discontinues marketing for economic reasons, as it had done in the past. The only cause for product removal from the publication will be for safety reasons. Products discontinued from marketing will be flagged in the Cumulative Supplement and future editions of this publication with the "a" symbol to designate their nonmarketed status.

III. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

DESCRIPTION OF REPORT

The following report provides summary counts derived from product information in the Drug Product List and the current cumulative supplement. The counts appear in two sections. Section A. refers to the products in the List and Section B. to products in the current cumulative supplement. A new column of data will appear in Section A. each three-month period following July '84. Section A. therefore will provide baseline and quarterly data while Section B. provides monthly activity.

USE OF REPORT

From the data presented under Section B., users should be able to observe such things as (1) newly approved, DESI effective and remarketed drug products which are added to the List; (2) products that are being removed from the List as the result of withdrawal of approval, changes from prescription to over-the-counter status and discontinued marketing of products; and, (3) trends in approval of products as either multisource or single source during each month within the quarter. The report does not reflect category changes from multisource to single source and vice versa. However, the net gain that results from all additions, deletions and category changes is reflected in the quarterly counts for multisource and single source products.

Drug Product Definition

For this report, a drug product is the representation in the Drug Product List of an active moiety (includes molecular entity and its salts, esters and derivatives) either as a single entity or as a combination product, provided in a specific dosage form and strength for a given route of administration marketed by a firm under a particular generic or trade name.

New Molecular Entity

The active moiety has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or part of a combination.

Drug Product Count

This report provides counts in several categories from the list composed of domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Counts of products still pending in the DESI review are not provided. Excluded also are those approved drug products marketed by distributors; those marketed solely abroad; and products now regarded as medical devices, biologics or foods.

A. COUNTS CUMULATIVE BY QUARTERS

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

CATEGORIES COUNTED	JULY '84 (BASELINE)	OCT '84	JAN '85	APR '85
DRUG PRODUCTS LISTED	7415	7609	7746	7890
SINGLE SOURCE	2005 (27.0%)	2045 (26.9%)	2077 (26.8%)	2078 (26.3%)
MULTISOURCE (1)	5410 (72.9%)	5564 (73.1%)	5669 (73.2%)	5812 (73.7%)
NOT THERAPEUTICALLY EQUIVALENT	4595 (59.2%)	4497 (59.1%)	4598 (59.4%)	4709 (59.6%)
EXCEPTIONS (2)	999 (13.4%)	1032 (13.5%)	1038 (13.4%)	1068 (13.5%)
NEW MOLECULAR ENTITIES APPROVED	18 (0.3%)	26 (0.3%)	23 (0.3%)	26 (0.3%)
NUMBER OF APPLICANTS	295	300	304	307

B. ACTIVITY FOR SUPPLEMENT NUMBER 9

CUMULATIVE

DRUG PRODUCTS ADDED:	40	40	40
NEWLY APPROVED	37	37	37
DESI EFFECTIVE	3	3	3
REMARKETED	0	0	0
DRUG PRODUCTS REMOVED:	28	28	28
WITHDRAWN APPROVAL	0	0	0
RX TO OTC SWITCH	0	0	0
DISCONTINUED MARKETING	28	28	28
NET GAIN IN DRUG PRODUCTS	12	12	12
SINGLE SOURCE PRODUCTS APPROVED	12	12	12
MULTISOURCE DRUG PRODUCTS APPROVED	28	28	28
NEW MOLECULAR ENTITIES APPROVED:	3	3	3
AS THE ENTITY	3	3	3
AS A SALT, ESTER OR DERIVATIVE	0	0	0
OF THE ENTITY	0	0	0

(1) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (I.E., AVAILABLE FROM MORE THAN ONE APPLICANT)
(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE 1-5 OF THE LIST)

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE SUPPLEMENT NUMBER 9 / AUGUST '84 - MAY '85

1

ACEBUTOLOL HYDROCHLORIDE (PAGE 3-1)

CAPSULE; ORAL

SECTRAL

IVES LABS/AMHO

EQ 200MG BASE#

EQ 400MG BASE#

N 18917

N 18917

ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

TABLET; ORAL

BUTALBITAL AND ACETAMINOPHEN

DANBURY PHARMACAL

325MG;50MG#

N 87550

ACETAMINOPHEN; BUTALBITAL; CAFFEINE (PAGE 3-1)

CAPSULE; ORAL

BUTALBITAL, ACETAMINOPHEN, CAFFEINE

AB DM GRAHAM LABS

325MG;50MG;40MG#

N 88758

AB

325MG;50MG;40MG#

N 88765

AB

325MG;50MG;40MG#

N 89067

ESGIC

AB GILBERT LABORATORIES

325MG;50MG;40MG#

N 88825

TABLET; ORAL

ESGIC

AB GILBERT LABORATORIES

325MG;50MG;40MG#

N 87629

FIORICET

AB SANDOZ PHARMS/SANDOZ

325MG;50MG;40MG#

N 88616

REPAN

AB DM GRAHAM LABS

325MG;50MG;40MG#

N 87804

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA ZENITH LABORATORIES

300MG;60MG

N 87083

ACETAMINOPHEN W/ CODEINE #2

AA LEIMON

300MG;15MG#

N 88627

ACETAMINOPHEN W/ CODEINE #3

AA LEIMON

300MG;30MG#

N 88628

ACETAMINOPHEN W/ CODEINE #4

AA LEIMON

300MG;60MG#

N 88629

/AA/ /ACETAMINOPHEN W/ CODEINE PHOSPHATE #4/

/ZENITH LABORATORIES/ 300MG;60MG/

/N 87633/

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-2)

CAPSULE; ORAL

ACETAMINOPHEN AND HYDROCODONE BITARTRATE

AA

CENTRAL PHARMS

500MG;5MG#

N 88898

TABLET; ORAL

ACETAMINOPHEN AND HYDROCODONE BITARTRATE

/CENTRAL PHARMS/

/500MG;5MG/

/N 87757/

CO-RESC

CENTRAL PHARMS

500MG;5MG

N 87757

HYDROCODONE BITARTRATE W/ ACETAMINOPHEN

AA

BARR LABORATORIES

500MG;5MG#

N 88577

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

CAPSULE; ORAL

TYLOX

MCNEIL PHARM

500MG;5MG#

N 88790

TYLOX-325

MCNEIL PHARM

325MG;5MG#

N 88246

TABLET; ORAL

/CO-RESC/

OXYCET

AA

HALSEY DRUG

325MG;5MG#

N 87463

ACETIC ACID, GLACIAL (PAGE 3-3)

SOLUTION/DROPS; OTIC

ACETIC ACID

AT

THAMES PHARMACAL

22#

N 88638

ACETIC ACID, GLACIAL; HYDROCORTISONE (PAGE 3-3)

SOLUTION/DROPS; OTIC

HYDROCORTISONE AND ACETIC ACID

AT

THAMES PHARMACAL

22;12#

N 88759

ACYCLOVIR (PAGE 3-4)

CAPSULE; ORAL

ZOVIRAX

BURROUGHS WELLCOME

200MG#

N 18828

ALBUTEROL SULFATE (PAGE 3-5)

SYRUP; ORAL

PROVENTIL

SCHERING

EQ 2MG BASE/5ML#

N 18062

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AMITRIPTYLINE HYDROCHLORIDE (PAGE 3-10)

TABLET; ORAL			
<u>AMITRIPTYLINE HCL</u>			
AB	SIDMAK LABORATORIES	10MG#	N 88883
AB		100MG#	N 88887
AB		150MG#	N 88888
BP	SUPERPHARM	10MG#	N 88853
BP		25MG#	N 88854
BP		50MG#	N 88855
BP		75MG#	N 88856
BP		100MG#	N 88857

AMMONIUM LACTATE (PAGE 3-12)

LOTION; TOPICAL			
<u>AMMONIUM LACTATE</u>			
	BRISTOL-MEYERS	EQ 12% ACID#	N 19155

AMOXICILLIN; POTASSIUM CLAVULANATE (PAGE 3-13)

POWDER FOR RECONSTITUTION; ORAL			
<u>AUGMENTIN '125'</u>			
	BEECHAM LABS/BEECHAM	125MG/5ML;	
		EQ 31.25MG ACID/5ML#	N 50575
<u>AUGMENTIN '250'</u>			
	BEECHAM LABS/BEECHAM	250MG/5ML;EQ 62.5MG ACID/5ML#	N 50575
TABLET; ORAL			
<u>AUGMENTIN '250'</u>			
	BEECHAM LABS/BEECHAM	250MG;EQ 125MG ACID#	N 50564
<u>AUGMENTIN '500'</u>			
	BEECHAM LABS/BEECHAM	500MG;EQ 125MG ACID#	N 50564

AMPHETAMINE SULFATE (PAGE 3-13)

TABLET; ORAL			
<u>AMPHETAMINE SULFATE</u>			
	LANNETT	5MG#	N 83901
		10MG#	N 83901

AMPICILLIN SODIUM (PAGE 3-14)

INJECTABLE; INJECTION			
<u>AMPICILLIN SODIUM</u>			
AP	ELI LILLY	EQ 500MG BASE/VIAL#	N 62565
AP		EQ 1GM BASE/VIAL#	N 62565

AMPICILLIN/AMPICILLIN TRIHYDRATE (PAGE 3-14)

CAPSULE; ORAL			
<u>AMPCICILLIN</u>			
	DRUMMER/PHOENIX	EQ 250MG BASE	N 61387
		EQ 500MG BASE	N 61387

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-16)

CAPSULE; ORAL			
<u>BUTALBITAL W/ ASPIRIN AND CAFFEINE</u>			
	CHELSEA LABORATORIES	325MG;50MG;40MG#	N 86231

TABLET; ORAL

AB	<u>BUTALBITAL COMPOUND</u>	325MG;50MG;40MG#	N 85441
	ZENITH LABORATORIES		

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE (PAGE 3-16)

CAPSULE; ORAL			
<u>PROPOXYPHENE COMPOUND 65</u>			
AA	LEMON	389MG;32.4MG;65MG#	N 89025
AA	ZENITH LABORATORIES	389MG;32.4MG;65MG#	N 83077
<u>PROPOXYPHENE HCL W/ ASPIRIN AND CAFFEINE</u>			
AA	CHELSEA LABORATORIES	389MG;32.4MG;65MG#	N 85732

ASPIRIN; METHOCARBAMOL (PAGE 3-17)

TABLET; ORAL			
<u>/METHOCARBAMOL 'A' ASPIRIN/</u>			
<u>METHOCARBAMOL AND ASPIRIN</u>			

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE (PAGE 3-18)

TABLET; ORAL			
<u>LOSEN</u>			
> ADD >	AA	SUPERPHARM	0.025MG;2.5MG#
> ADD >			

AURANOFIN (PAGE 3-18)

CAPSULE; ORAL			
<u>RIDAURA</u>			
> ADD >		SK&F LABORATORIES	3MG#
> ADD >			
> ADD >			

BENZOYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

GEL; TOPICAL			
<u>BENZAMYCIN</u>			
	DERMIK/RORER	5%;32#	N 50557

[illegible]

(Page 3-25)

BROMOPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR; ORAL

DIFHTERAP
DAY LABORATORIES
4MS/SML:25MS/SML

N 06687

BROMAHATE
NAT PHARM MF6/BARRE
4MS/SML:25MS/SML

N 06669

PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-25)
 RHOENHAIPTHEIN MALEATE/ DEXTROMETHORPHAN HYDROBROMIDE,
 SYRUP, ORAL
 PROMETHEIN DM
 NATL PHARM HFA/BARE 2MG/SML:10MG/SML:30MG/SML
 DEXTINE-DX
 AH ROBINS
 2MG/SML:10MG/SML:30MG/SML
 2MG/SML:10MG/SML:30MG/SML
 N 11699 N 19279

11699	N	12.5HG/5ML	2MS/5ML:10MG/5ML	12.5HG/5ML	11699
60723	N	12.5HG/5ML	2MS/5ML:10MG/5ML	12.5HG/5ML	60723
60904	N	12.5HG/5ML	2MS/5ML:10MG/5ML	12.5HG/5ML	60904

N	68626	AMREX RAY LABORATORIES	12.5MG/SHT;10MG/SML
N	69319	AMREX FARROW LABORATORIES	12.5MG/SHT;10MG/SML
N	68343	BROMANLY NATL PHARM MFG/BARRK	12.5MG/SHT;10MG/SML

PHENTHRANIPYRROLAMINE HYDROCHLORIDE (PAGE 3-25)

ROMODIPHEHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE (PAGE 3-24)

BUPRENORPHINE HYDROCHLORIDE (PAGE 3-26)

INJECTABLE; INJECTION

/BUPRENEX/

/NORMAN EATON/P&G/

/Ed. 0.3MG BASE/ML/

/N 18801/

BUTABARBITAL SODIUM (PAGE 3-26)

ELIXIR; ORAL

/SODIUM BUTABARBITAL/

BUTABARBITAL SODIUM

TABLET; ORAL

BUTABARBITAL SODIUM

LEMON

15MG

N 88632

30MG

N 88631

> ADD > AA
> ADD > AA

CALCITONIN (PAGE 3-27)

INJECTABLE; INJECTION

CALCIMAR

/ARMOUR PHARM/

/400 IU/ML/

/400 IU/VIAL/

/N 17769/

/N 17497/

ARMOUR PHARM

200 IU/ML

400 IU/VIAL

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-28)

SOLUTION; INTRAPERITONEAL

DELFLX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT DELMED 25.7MG/100ML; 1.5GM/100ML;
15.2MG/100ML; 567MG/100ML;
392MG/100ML N 18883

DELFLX W/ DEXTROSE 1.5% LOW MAGNESIUM IN PLASTIC CONTAINER

AT DELMED 25.7MG/100ML; 1.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N 18883

DELFLX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

AT DELMED 25.7MG/100ML; 2.5GM/100ML;
15.2MG/100ML; 567MG/100ML;
392MG/100ML N 18883

DELFLX W/ DEXTROSE 2.5% LOW MAGNESIUM IN PLASTIC CONTAINER

AT DELMED 25.7MG/100ML; 2.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N 18883

DELFLX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AT DELMED 25.7MG/100ML; 4.25GM/100ML;
15.2MG/100ML; 567MG/100ML;
392MG/100ML N 18883

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-28)

SOLUTION; INTRAPERITONEAL

DELFLX W/ DEXTROSE 4.25% LOW MAGNESIUM IN PLASTIC CONTAINER

AT DELMED 25.7MG/100ML; 4.25GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N 18883

DIANEAL PD-1 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT TRAVENOL LABS 25.7MG/100ML; 1.5GM/100ML;
15.2MG/100ML; 567MG/100ML;
392MG/100ML N 17512

DIANEAL PD-1 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

AT TRAVENOL LABS 25.7MG/100ML; 2.5GM/100ML;
15.2MG/100ML; 567MG/100ML;
392MG/100ML N 17512

DIANEAL PD-1 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AT TRAVENOL LABS 25.7MG/100ML; 4.25GM/100ML;
15.2MG/100ML; 567MG/100ML;
392MG/100ML N 17512

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-29)

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND

LACTATED RINGER'S IN PLASTIC CONTAINER

AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
105MG/100ML; 600MG/100ML;
310MG/100ML N 19367

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND

LACTATED RINGER'S IN PLASTIC CONTAINER

AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
105MG/100ML; 600MG/100ML;
310MG/100ML N 19367

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND

LACTATED RINGER'S IN PLASTIC CONTAINER

AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
105MG/100ML; 600MG/100ML;
310MG/100ML N 19367

POTASSIUM CHLORIDE 25MEQ IN DEXTROSE 5% AND

LACTATED RINGER'S IN PLASTIC CONTAINER

AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
105MG/100ML; 600MG/100ML;
310MG/100ML N 19367

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND

LACTATED RINGER'S IN PLASTIC CONTAINER

AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
105MG/100ML; 600MG/100ML;
310MG/100ML N 19367

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND

LACTATED RINGER'S IN PLASTIC CONTAINER

AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
105MG/100ML; 600MG/100ML;
310MG/100ML N 19367

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CEFOXITIN SODIUM; SODIUM CHLORIDE (PAGE 3-33)

INJECTABLE; INJECTION
MEFOXIN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
MS&D/MERCK EQ 20MG BASE/ML; 9MG/ML N 50581
EQ 40MG BASE/ML; 9MG/ML N 50581

CEFTIZOXIME SODIUM; DEXTROSE (PAGE 3-33)

INJECTABLE; INJECTION
CEFIZOX IN DEXTROSE 5% IN PLASTIC CONTAINER
SK&F LABORATORIES EQ 20MG BASE/ML; 50MG/ML N 50589
EQ 40MG BASE/ML; 50MG/ML N 50589

CEFTRIAXONE SODIUM (PAGE 3-33)

INJECTABLE; INJECTION
ROCEPHIN
HOFFMANN-LA ROCHE EQ 250MG BASE/VIAL N 50585
EQ 250MG BASE/VIAL N 42510
EQ 500MG BASE/VIAL N 50585
EQ 500MG BASE/VIAL N 62510
EQ 1GM BASE/VIAL N 50585
EQ 1GM BASE/VIAL N 62510
EQ 2GM BASE/VIAL N 50585
EQ 10GM BASE/VIAL N 50585

CELLULOSE SODIUM PHOSPHATE (PAGE 3-34)

POWDER; ORAL
CALCIBIND
MISSION PHARMACAL 300GM/BOTM N 18757

CEPHALOTHIN SODIUM (PAGE 3-34)

INJECTABLE; INJECTION
SEPHALOTHIN
INTL MEDICATION SYS EQ 1GM BASE/VIAL N 62426
EQ 2GM BASE/VIAL N 62426
EQ 4GM BASE/VIAL N 62426
EQ 500MG BASE/VIAL N 62426

CHLORDIAZEPOXIDE HYDROCHLORIDE (PAGE 3-37)

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL
LEMMON 5MG N 88705
10MG N 88706
25MG N 88707
5MG N 88987
10MG N 88988
25MG N 88988

CHLOROTHIAZIDE (PAGE 3-38)

TABLET; ORAL
CHLOROTHIAZIDE
DRUMMER/PHOENIX 250MG N 85485

CHLORPROMAZINE HYDROCHLORIDE (PAGE 3-40)

CONCENTRATE; ORAL
CHLORPROMAZINE HCL
ROXANE LABORATORIES 30MG/ML N 88157
100MG/ML N 88158
CHLORPROMAZINE HCL INTENSOL
ROXANE LABORATORIES 30MG/ML N 88157
100MG/ML N 88158
TABLET; ORAL
CHLORPROMAZINE HCL
CORD LABORATORIES 10MG N 80439
25MG N 80439
50MG N 80439
100MG N 80439
200MG N 80439
SONNATINE
CORD LABORATORIES 10MG N 80439
25MG N 80439
50MG N 80439
100MG N 80439
200MG N 80439

CHLORPROPAMIDE (PAGE 3-42)

TABLET; ORAL
CHLORPROPAMIDE
BARR LABORATORIES 100MG N 88812
250MG N 88813
CHELSEA LABORATORIES 100MG N 88865
COLMED LABORATORIES 100MG N 88708
250MG N 88709
CORD LABORATORIES 100MG N 88725
250MG N 88726
DANBURY PHARMACAL 100MG N 88852
250MG N 88826
DURAMED PHARMS 100MG N 88918
250MG N 88919
LEMMON 100MG N 88768
SIDMAK LABORATORIES 100MG N 88921
250MG N 88922
SUPERPHARM 100MG N 88694
250MG N 88695
ZENITH LABORATORIES 100MG N 88940
BLUCANTIDE
LEMMON 250MG N 88641

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CROMOLYN SODIUM (PAGE 3-48)

SOLUTION/DROPS; OPHTHALMIC
OPTICROM
FISONS

4%
N 18155

CYCLOPHOSPHAMIDE (PAGE 3-50)

INJECTABLE; INJECTION
CYTOXAN

AP /HEAD. JOHNSON/B-N/ 100MG/VIAL/ N 12142
AP /HEAD. JOHNSON/B-N/ 200MG/VIAL/ N 12142
AP /HEAD. JOHNSON/B-N/ 500MG/VIAL/ N 12142
AP /HEAD. JOHNSON/B-N/ 1GM/VIAL/ N 12142
AP /HEAD. JOHNSON/B-N/ 2GM/VIAL/ N 12142

AP BRISTOL LABS/B-N 100MG/VIAL N 12142
AP BRISTOL LABS/B-N 200MG/VIAL N 12142
AP BRISTOL LABS/B-N 500MG/VIAL N 12142
AP BRISTOL LABS/B-N 1GM/VIAL N 12142
AP BRISTOL LABS/B-N 2GM/VIAL N 12142

TABLET; ORAL
CYTOXAN

HEAD. JOHNSON/B-N/ 15MG/ N 12141
HEAD. JOHNSON/B-N/ 50MG/ N 12141
BRISTOL LABS/B-N 25MG N 12141
BRISTOL LABS/B-N 50MG N 12141

CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-51)

TABLET; ORAL

CYPROHEPTADINE HCL
AM THERAPEUTICS

4MG
N 88798

DESERPIDINE; METHYLOTHIAZIDE (PAGE 3-52)

TABLET; ORAL

BP ENDURONYL 0.25MG;5MG N 12775
BP ABBOTT LABORATORIES 0.25MG;5MG N 12775
BP ENDURONYL FORTE 0.5MG;5MG N 12775
BP ABBOTT LABORATORIES 0.5MG;5MG N 12775
BP METHYLOTHIAZIDE AND DESERPIDINE
BP BOLAR PHARMACEUTICAL 0.25MG;5MG N 88486
BP BOLAR PHARMACEUTICAL 0.5MG;5MG N 88452

DESONIDE (PAGE 3-53)

CREAM; TOPICAL

DESONEN

AB OWEN LABS/DERM PRODS 0.05% N 19048
AB TRIDESTILON
AB MILES PHARMS/MILES 0.05% N 17010

DESOXIMETASONE (PAGE 3-53)

OINTMENT; TOPICAL

TOPICORT

HOECHST-ROUSSEL

0.05%
N 18594

DEXAMETHASONE (PAGE 3-53)

/CREAM; TOPICAL/

/HEXADROL/

/CREAMON/ARZONA/

0.05%
N 13306

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-55)

OINTMENT; OPHTHALMIC

DEXACIDIN

AT COOPERVISION PHARMS 0.1%;EQ 3.5MG BASE/GM;
10,000 UNITS/GM N 62566

SUSPENSION/DROPS; OPHTHALMIC

DEXACIDIN

AT COOPERVISION PHARMS 0.1%;EQ 3.5MG BASE/ML;
10,000 UNITS/ML N 62544

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-55)

SOLUTION/DROPS; OPHTHALMIC

DEXAMETHASONE SODIUM PHOSPHATE

AT CARTER-GLOSAU LABS EQ 0.1% PHOSPHATE N 88771

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE (PAGE 3-56)

SOLUTION/DROPS; OPHTHALMIC

NEODECADRON

AT MSD/MERCK EQ 0.1% PHOSPHATE;
EQ 3.5MG BASE/ML N 50322

NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

AT PHARMAFAIR EQ 0.1% PHOSPHATE;
EQ 3.5MG BASE/ML N 62539

/DEMBROMPHENTRAMINE MALEATE; PSEUDOPHEDRINE SULFATE/ (PAGE 3-56)

/TABLET; ORAL/

/DISOPHROL/

/SCHERING/

2MG;60MG/

N 12344

DEXTROAMPHETAMINE SULFATE (PAGE 3-56)

TABLET; ORAL

DEXTROAMPHETAMINE SULFATE

3 VITARINE/PHOENIX

3 10MG

N 84986

N 85892

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> ADD > AA
> ADD > AA

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DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

(PAGE 3-57)

SYRUP; ORAL

PHEGEMAN W/ DEXTROMETHORPHAN

MYTEL LABS/ALMO 15MG/5ML;6.25MG/5ML

PROMETH W/ DEXTROMETHORPHAN

NATL PHARM HF6/BARE 15MG/5ML;6.25MG/5ML

PROMETHAZINE DM

BAT LABORATORIES 15MG/5ML;6.25MG/5ML

DEXTROSE (PAGE 3-57)

INJECTION

DEXTROSE 30% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 30G/100ML

TRAVENOL LABS 30G/100ML

DEXTROSE 30.5% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 30.5G/100ML

DEXTROSE 6% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 60G/100ML

ABBOTT LABORATORIES 60G/100ML

N 19346

DEXTROSE; HEPARIN SODIUM (PAGE 3-50)

INJECTION

HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5%

ABBOTT LABORATORIES 10,000 UNITS/100ML

HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC

CONTAINER

HEPARIN SODIUM 1000 UNITS AND DEXTROSE 5% IN PLASTIC

CONTAINER

HEPARIN SODIUM 2000 UNITS AND DEXTROSE 5% IN PLASTIC

CONTAINER

HEPARIN SODIUM 12,500 UNITS IN DEXTROSE 5%

ABBOTT LABORATORIES 5G/100ML;5.000 UNITS/100ML

HEPARIN SODIUM 12,500 UNITS IN DEXTROSE 5% IN PLASTIC

CONTAINER

HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC

CONTAINER

HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC

CONTAINER

HEPARIN SODIUM 2500 UNITS IN DEXTROSE 5% IN PLASTIC

CONTAINER

HEPARIN SODIUM 5000 UNITS AND DEXTROSE 5% IN PLASTIC

CONTAINER

AM HCSAM/AM HOSP 5G/100ML;5.000 UNITS/100ML

AM HCSAM/AM HOSP 5G/100ML;5.000 UNITS/100ML

AM HCSAM/AM HOSP 5G/100ML;1.000 UNITS/100ML

N 19130

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 3-50)

INJECTION

LIDOCAINE MCL W/ DEXTROSE

ABBOTT LABORATORIES 7.5%:5%

N 63914

XILCANE M/ DEXTROSE

ASTRA PHARM PRODS 7.5%:1.5%

N 16297

XILCANE W/ GLUCOSE

ASTRA PHARM PRODS 7.5%:5%

N 10496

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 3-50)

INJECTION

LIDOCAINE MCL W/ DEXTROSE

ABBOTT LABORATORIES 7.5%:5%

XILCANE M/ DEXTROSE

ASTRA PHARM PRODS 7.5%:1.5%

XILCANE W/ GLUCOSE

ASTRA PHARM PRODS 7.5%:5%

N 10496

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM

PHOSPHATE, DIBASIC; SODIUM ACETATE (PAGE 3-50)

INJECTION

ISOLYTE P M/ DEXTROSE 5% IN PLASTIC CONTAINER

AM HCSAM/AM HOSP 5G/100ML;31MG/100ML;130MG/100ML

26MG/100ML;32MG/100ML

N 19025

DEXTROSE; OXYTOCIN (PAGE 3-59)

INJECTION

OXYTOCIN 10 USP UNITS IN DEXTROSE 5%

ABBOTT LABORATORIES 5G/100ML;2 USP UNITS/100ML

OXYTOCIN 20 USP UNITS IN DEXTROSE 5%

ABBOTT LABORATORIES 5G/100ML;2 USP UNITS/100ML

OXYTOCIN 5 USP UNITS IN DEXTROSE 5%

ABBOTT LABORATORIES 5G/100ML;1 USP UNIT/100ML

N 19165

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE (PAGE 3-60)

INJECTION

POTASSIUM CHLORIDE 10MEG IN DEXTROSE 5% AND SODIUM

CHLORIDE 0.9% IN PLASTIC CONTAINER

TRAVENOL LABS 5G/100ML;75MG/100ML

90MG/100ML

5G/100ML;150MG/100ML

N 19306

POTASSIUM CHLORIDE 20MEG IN DEXTROSE 5% AND SODIUM

CHLORIDE 0.9% IN PLASTIC CONTAINER

TRAVENOL LABS 5G/100ML;130MG/100ML

90MG/100ML

5G/100ML;300MG/100ML

N 19306

POTASSIUM CHLORIDE 30MEG IN DEXTROSE 5% AND SODIUM

CHLORIDE 0.9% IN PLASTIC CONTAINER

TRAVENOL LABS 5G/100ML;224MG/100ML

90MG/100ML

5G/100ML;300MG/100ML

N 19306

POTASSIUM CHLORIDE 40MEG IN DEXTROSE 5% AND SODIUM

CHLORIDE 0.9% IN PLASTIC CONTAINER

TRAVENOL LABS 5G/100ML;300MG/100ML

90MG/100ML

N 19306

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE (PAGE 3-60)

INJECTABLE; INJECTION
POTASSIUM CHLORIDE 5MG IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
 AP TRAVENOL LABS 5GM/100ML;150MG/100ML; 900MG/100ML N 19308

DEXTROSE; THEOPHYLLINE (PAGE 3-62)

INJECTABLE; INJECTION
THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER
 AP TRAVENOL LABS 5GM/100ML;40MG/100ML N 18649
 AP 5GM/100ML;80MG/100ML N 18649
 AP 5GM/100ML;160MG/100ML N 18649
 AP 5GM/100ML;200MG/100ML N 18649
 AP 5GM/100ML;400MG/100ML N 18649
THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER
 AP ABBOTT LABORATORIES 5GM/100ML;40MG/100ML N 19211
 AP 5GM/100ML;80MG/100ML N 19211
 AP 5GM/100ML;160MG/100ML N 19211
 AP 5GM/100ML;200MG/100ML N 19211
 AP 5GM/100ML;400MG/100ML N 19211
THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER
 AP AM MCGAW/AM HOSP 5GM/100ML;40MG/100ML N 19083
THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER
 AP AM MCGAW/AM HOSP 5GM/100ML;80MG/100ML N 19083
THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER
 AP AM MCGAW/AM HOSP 5GM/100ML;160MG/100ML N 19083
THEOPHYLLINE 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER
 AP AM MCGAW/AM HOSP 5GM/100ML;200MG/100ML N 19212
THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER
 AP AM MCGAW/AM HOSP 5GM/100ML;400MG/100ML N 19212

DIATRIZOATE MEGLUMINE (3-62)

INJECTABLE; INJECTION
HYPAGUE
 /AP/ /WINTHROP LABS/STERIL/100/ /N 16403/
 /AP/ /WINTHROP LABS/STERIL/200/ /N 16403/
 AP HYPAGUE MEGLUMINE 30% N 16403
 AP HYPAGUE MEGLUMINE 60% N 16403
 SOLUTION; URETHRAL
 HYPAGUE-CYSTO
 /AT/ /WINTHROP LABS/STERIL/300/ /N 16403/
 AT WINTHROP-BREON/STERIL 30% N 16403

DIATRIZOATE SODIUM (PAGE 3-63)

INJECTABLE; INJECTION
HYPAGUE
 /AP/ /WINTHROP LABS/STERIL/100/ /N 09561/
 /AP/ /WINTHROP LABS/STERIL/200/ /N 09561/
 AP WINTHROP-BREON/STERIL 20% N 09561

SOLUTION; URETERAL

HYPAGUE
 /WINTHROP LABS/STERIL/200/ /N 09561/
 WINTHROP-BREON/STERIL 20% N 09561

DICYCLIMINE HYDROCHLORIDE (PAGE 3-64)

CAPSULE; ORAL
 BENTYL
 MERRELL DOW/DOW CHEM 10MG N 07409
 INJECTABLE; INJECTION
 BENTYL
 MERRELL DOW/DOW CHEM 10MG/ML N 08370
 SYRUP; ORAL
 BENTYL
 MERRELL DOW/DOW CHEM 10MG/5ML N 07961
 TABLET; ORAL
 BENTYL
 MERRELL DOW/DOW CHEM 20MG N 07409

DIETHYLPROPION HYDROCHLORIDE (PAGE 3-65)

TABLET; ORAL
DIETHYLPROPION HCL
 AA LEMMON 25MG N 88642

DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

INJECTABLE; INJECTION
 EMBOLEX
 SANDOZ PHARMS/SANDOZ 0.5MG/0.5ML;2,500 UNITS/0.5ML; 5.33MG/0.5ML N 18885
 0.5MG/0.7ML;5,000 UNITS/0.7ML; 7.46MG/0.7ML N 18885

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-67)

CAPSULE; ORAL
DIPHENHYDRAMINE HCL
 SUPERPHARM 25MG N 89040
 50MG N 89041

ERYTHROMYCIN (PAGE 3-73)

OINTMENT; TOPICAL
 AKNE-MYCIN
 HERMAL PHARM LABS 2% N 50584

 SOLUTION; TOPICAL
SANSAC
 OWEN LABS/DERM PRODS 2% N 62522

 SWAB; TOPICAL
 ERYCETTE
 ORTHO PHARMACEUTICAL 2% N 50594

ERYTHROMYCIN ETHYLSUCCINATE (PAGE 3-74)

SUSPENSION; ORAL
ERYTHROMYCIN ETHYLSUCCINATE
 AB PHARMAFAIR EQ 200MG BASE/5MLM N 62559
 AB EQ 400MG BASE/5MLM N 62558

ERYTHROMYCIN LACTOBIONATE (PAGE 3-75)

INJECTABLE; INJECTION
ERYTHROMYCIN
 AP ELKINS-SINN/AHROBINS EQ 500MG BASE/VIALM N 62563
 AP EQ 1GM BASE/VIALM N 62563
ERYTHROMYCIN LACTOBIONATE
 AP ABBOTT LABORATORIES EQ 500MG BASE/VIAL N 50182
 AP EQ 1GM BASE/VIAL N 50182

ESTROGENS, CONJUGATED (PAGE 3-76)

TABLET; ORAL
 CONJUGATED ESTROGENS
 BS ZENITH LABORATORIES 0.3MGM N 88569

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE (PAGE 3-78)

TABLET; ORAL-21
 /DEBULEN/
 DEMULEN 1/50-21

 TABLET; ORAL-28
 /DEBULEN-28/
 DEMULEN 1/50-28

ETHINYL ESTRADIOL; LEVONORGESTREL (PAGE 3-78)

TABLET; ORAL-21
 TRIPHASIL-21
 MYETH LABS/AMHO 0.03MG, 0.04MG, 0.03MG;
 0.05MG, 0.075MG, 0.125MG N 19192

 TABLET; ORAL-28
 TRIPHASIL-28
 MYETH LABS/AMHO 0.03MG, 0.04MG, 0.03MG;
 0.05MG, 0.075MG, 0.125MG N 19190

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE (PAGE 3-79)

TABLET; ORAL-21
 /LOESTRIN 1.5/30/
 LOESTRIN 21 1.5/30

ETIDRONATE DISODIUM (PAGE 3-81)

TABLET; ORAL
 DIDRONEL
 NORWICH EATON/P&G 400MG N 17831

FENTANYL CITRATE (PAGE 3-81)

INJECTABLE; INJECTION
FENTANYL CITRATE
 AP ABBOTT LABORATORIES EQ 0.05MG BASE/MLM N 19115

FLUNISOLIDE (PAGE 3-82)

AEROSOL; INHALATION
 BRONALIDE
 SYNTEX LABS/SYNTEX 0.025MG/INHLM N 18340

FLUOCINOLONE ACETONIDE (PAGE 3-82)

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE
 AT BAY LABORATORIES 0.01% N 88757
 AT 0.025% N 88756
 AT PHARMAFAIR 0.01% N 88499
 AT 0.025% N 88506

FLUONID
 AT HERBERT LABS/ALLERGN 0.025% N 87156
 /AT/ /HARION LABORATORIES/ /0.012/ /N 88434/
 /AT/ /0.0252/ /N 88434/

HEPARIN SODIUM (PAGE 3-91)

INJECTABLE; INJECTABLE			
<u>HEPARIN LOCK FLUSH</u>			
AP	LYPHOMED	100 UNITS/ML	N 17651
AP	SOLOPAK LABORATORIES	10 UNITS/ML	N 88457
AP		10 UNITS/ML	N 88580
AP		100 UNITS/ML	N 88581
<u>HEPARIN SODIUM</u>			
/AP/	ELKINS-SINN/AMROBINS/	20,000 UNITS/ML/	/N 17637/
/AP/		40,000 UNITS/ML/	/N 17637/
		250 UNITS/ML	/N 17637/

HEPARIN SODIUM; SODIUM CHLORIDE (PAGE 3-93)

INJECTABLE; INJECTION			
HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.9%			
	ABBOTT LABORATORIES	10,000 UNITS/100ML;	
		900MG/100ML	N 18911
AP	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45%		
	ABBOTT LABORATORIES	10,000 UNITS/100ML;	
		450MG/100ML	N 18911
AP	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.9%		
	ABBOTT LABORATORIES	5,000 UNITS/100ML;	
		900MG/100ML	N 18911
AP	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9%		
	ABBOTT LABORATORIES	5,000 UNITS/100ML;	
		900MG/100ML	N 18911
AP	HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.45%		
	ABBOTT LABORATORIES	100 UNITS/ML; 4.5MG/ML	N 18911

HEPARIN SODIUM; SODIUM CHLORIDE - IN PLASTIC (PAGE 3-93)

INJECTABLE; INJECTION			
<u>HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9%</u>			
AP	AM MCGAW/AM HOSP	200 UNITS/100ML; 900MG/100ML	N 19042
<u>HEPARIN SODIUM 2000 UNITS IN SODIUM CHLORIDE 0.9%</u>			
AP	AM MCGAW/AM HOSP	200 UNITS/100ML; 900MG/100ML	N 19042
<u>HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9%</u>			
AP	AM MCGAW/AM HOSP	5,000 UNITS/100ML;	
AP		900MG/100ML	N 19135
<u>HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9%</u>			
AP	ABBOTT LABORATORIES	1,000 UNITS/100ML; 900MG/100ML	N 18916
AP	AM MCGAW/AM HOSP	1,000 UNITS/100ML;	
		900MG/100ML	N 19042

HEXACHLOROPHENE (PAGE 3-94)

EMULSION; TOPICAL			
<u>URGEX</u>			
AT	XTTRIUM LABS	32%	N 19055

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE (PAGE 3-95)

> DLT >
> ADD >
SYRUP; ORAL
/HYDROCODONE/
HYDROCODONE COMPOUND

HYDRALAZINE HYDROCHLORIDE (PAGE 3-95)

TABLET; ORAL			
<u>HYDRALAZINE HCL</u>			
AA	AMIDE PHARMACEUTICAL	25MG	N 88560
AA		50MG	N 88649
AA	ASCOT HOSP PHARMS	25MG	N 88310
AA		50MG	N 88311
AA	BARR LABORATORIES	10MG	N 88728
AA		100MG	N 88729
AA	CANALL	10MG	N 88846
AA		25MG	N 88847
AA		50MG	N 88848
AA		100MG	N 88849
AA	DRUMMER/PHOENIX	25MG	N 88088
AA	SUPERPHARM	10MG	N 88787
AA		25MG	N 88788
AA		50MG	N 88789

HYDROCHLOROTHIAZIDE (PAGE 3-96)

TABLET; ORAL			
<u>HYDROCHLOROTHIAZIDE</u>			
AB	LEMON	25MG	N 88924
AB		50MG	N 88923
AB	SUPERPHARM	25MG	N 88827
AB		50MG	N 88828
AB		100MG	N 88829

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE (PAGE 3-98)

TABLET; ORAL			
LOPRESSOR HCT 100/25			
	GEIGY/CIBA-GEIGY	25MG; 100MG	N 18303
LOPRESSOR HCT 100/50			
	GEIGY/CIBA-GEIGY	50MG; 100MG	N 18303
LOPRESSOR HCT 50/25			
	GEIGY/CIBA-GEIGY	25MG; 50MG	N 18303

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE (PAGE 3-98)

TABLET; ORAL			
<u>INDEPIDE</u>			
	AYERST LABS/AYD	125MG; 40MG/	/N 18031/
		125MG; 80MG/	/N 18031/

IMIPRAMINE HYDROCHLORIDE (PAGE 3-107)

TABLET; ORAL
SK-FRANKE
/AB/ SK&F LABORATORIES/ 10MG/
/AB/ 25MG/
/BP/ 50MG/
AB SK&F LABORATORIES 10MG
AB 25MG
BP 50MG

/N'18883/
/N'18883/
/N'18883/
N 83827
N 83827
N 83827

>_ADD_> AP
AP
AP
AP

KANAMYCIN SULFATE (PAGE 3-112)

INJECTABLE; INJECTION
KANAMYCIN SULFATE
CARTER-SLOGAU LABS EQ 1GM BASE/3MLM
KANTREX
BRISTOL LABS/B-M EQ 75MG BASE/2MLM
EQ 500MG BASE/2MLM
EQ 1GM BASE/3MLM

N 62520
N 62544
N 62564
N 62564

INDOMETHACIN (PAGE 3-108)

CAPSULE; ORAL
INDOMETHACIN
AB PAR PHARMACEUTICAL 25MG
AB 50MG
AB PARKE-DAVIS/W-L 25MG
AB 50MG

N 18829
N 18829
N 18806
N 18806

SUPPOSITORY; RECTAL
INDOCIN
MS&D RES LABS/MERCK 50MG

N 17814

INDOMETHACIN SODIUM TRIHYDRATE (PAGE 3-108)

INJECTABLE; INJECTION
INDOCIN I.V.
MS&D/MERCK EQ 1MG BASE/VIALM

N 18878

IODOHIPPURATE SODIUM, I-123 (PAGE 3-109)

INJECTABLE; INJECTION
NEPHROFLOW
MEDI-PHYSICS 1MCI/MLM

N 18289

IOPANOIC ACID (PAGE 3-109)

TABLET; ORAL
TELEPAQUE
/WINTHROP LABS/STERL/500MG/
WINTHROP-BREON/STERL 500MG

/N'08032/
N 08032

ISOETHARINE MESYLATE (PAGE 3-110)

AEROSOL; INHALATION
BRONKOMETER
/BREON LABS/STERLING/0.34MG/INH
BN BREON LABS/STERLING 0.34MG/INH
ISOETHARINE MESYLATE
BN NATL PHARM MFG/BARRE 0.34MG/INH

/N'12339/
N 12339
N 87858

LABETALOL HYDROCHLORIDE (PAGE 3-113)

INJECTABLE; INJECTION
NORMODYNE
SCHERING 5MG/MLM

N 18686

TABLET; ORAL
NORMODYNE
AB SCHERING 200MG
AB 300MG
AB 400MG

N 18667
N 18667
N 18667

TRANDATE
AB GLAXO 200MG
AB 300MG
AB 400MG

N 18716
N 18716
N 18716

LEUPROLIDE ACETATE (PAGE 3-113)

INJECTABLE; INJECTION
LUPRON
TAP PHARMACEUTICALS 1MG/0.2MLM

N 19010

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE (PAGE 3-114)

INJECTABLE; INJECTION
SCANDONEST L
AP DEPROCO 0.05MG/ML; 22M

N 88388

LIDOCAINE (PAGE 3-114)

AEROSOL; ORAL
XYLOCAINE
ASTRA PHARM PRODS 102M

N 14394

LIDOCAINE HYDROCHLORIDE (PAGE 3-115)

INJECTABLE; INJECTION
XYLOCAINE
ASTRA PHARM PRODS /52/

/N'18496/

SOLUTION; ORAL
LIDOCAINE HCL
AT ROYANE LABORATORIES/ 22M

N 88802

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METHYLCLOTHIAZIDE (PAGE 3-129)

TABLET; ORAL

<u>METHYLCLOTHIAZIDE</u>		
AB CHELSEA LABORATORIES	2.5MG	N 88750
AB	5MG	N 88724
AB COLMED LABORATORIES	5MG	N 88745

METHYLDOPA (PAGE 3-130)

TABLET; ORAL

<u>METHYLDOPA</u>		
AB MYLAN PHARMS	250MG	N 70075
AB	500MG	N 70076

METHYLPREDNISOLONE SODIUM SUCCINATE (PAGE 3-131)

INJECTABLE; INJECTION

<u>SOLU-MEDROL</u>		
UPJOHN	EQ 2GM BASE/VIAL	N 11856

METRONIDAZOLE (PAGE 3-133)

INJECTABLE; INJECTION

<u>METRONIDAZOLE</u>		
>_ADD_> AP INTL MEDICATION SYS	500MG/100ML	N 70004
AP LYPHOED	500MG/100ML	N 70071
AP <u>METRYL IV</u>		
LEHMON	500MG/100ML	N 70042

TABLET; ORAL

<u>METRONIDAZOLE</u>		
AB HALSEY DRUG	250MG	N 70021
AB PAR PHARMACEUTICAL	250MG	N 70040
AB	500MG	N 70039
AB SIDNAK LABORATORIES	250MG	N 70027
AB	500MG	N 70033
AB SUPERPHARM	250MG	N 70008
AB	500MG	N 70009
AB <u>METRYL</u>		
LEHMON	250MG	N 70035
AB <u>METRYL 500</u>		
LEHMON	500MG	N 70044
AB <u>SATRIO</u>		
SAVAGE LABS/ALTANA	250MG	N 70029

MICONAZOLE NITRATE (PAGE 3-134)

SUPPOSITORY; VAGINAL

MONISTAT 3		
ORTHO PHARMACEUTICAL	200MG	N 18888

MORPHINE SULFATE (PAGE 3-135)

INJECTABLE; INJECTION

DURAMORPH PF		
ELKINS-SINN/AHROBINS	0.5MG/ML	N 18565
	1MG/ML	N 18565

NAFCILLIN SODIUM (PAGE 3-135)

INJECTABLE; INJECTION

<u>NAFCILLIN</u>		
AP BRISTOL LABS/B-M	EQ 10GM BASE/VIAL	N 62527
AP <u>MALLPEN</u>		
BEECHAM LABS/BEECHAM	EQ 10GM BASE/VIAL	N 61999

NALBUPHINE HYDROCHLORIDE (PAGE 3-136)

INJECTABLE; INJECTION

MUBAIN		
DUPONT PHARMS/DUPONT	20MG/ML	N 18024

NALTREXONE HYDROCHLORIDE (PAGE 3-136)

TABLET; ORAL

TREXAN		
DUPONT PHARMS/DUPONT	50MG	N 18932

NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-137)

SOLUTION/DROPS; OPHTHALMIC

STATROL		
ALCON LABORATORIES	EQ 3.5MG BASE/ML;	
	16,250 UNITS/ML	N 62339

NONIFENSINE MALEATE (PAGE 3-140)

CAPSULE; ORAL

MERITAL		
HOECHST-ROUSSEL	25MG	N 18224
	50MG	N 18224

NOREPINEPHRINE BITARTRATE (PAGE 3-140)

INJECTABLE; INJECTION

LEVOPHED		
/BREON LABS/STERLING/	EQ 1MG BASE/ML/	N 07513/
WINTHROP-BREON/STERL	EQ 1MG BASE/ML	N 07513

INJECTABLE; INJECTION
/INJECTION YB 169 DTPA
/DIAGNOSTIC PRODS/3M/2MCI/ML/

/PENTATE CALCIUM TRISODIUM, YB-169 (PAGE 3-145)/

AB GEISY/CIBA-GEISY 100MG

AB SOLAR PHARMACEUTICAL 100MG

TABLET; ORAL

OXYPHENBUTAZONE (PAGE 3-143)

AA BAY LABORATORIES 100MG/5ML

AA PARK-DAVIS/M-L 100MG/5ML

ELIXIR; ORAL

OXYBUPHYLLINE (PAGE 3-143)

BEECHAM LABS/BEECHAM EQ 100M BASE/VIAL

INJECTABLE; INJECTION

OXYACILLIN SODIUM (PAGE 3-142)

> ADD > AI MNC LABORATORIES 100,000 UNITS/GM; 0.12M

> ADD > AI MNC LABORATORIES 100,000 UNITS/GM; 0.12M

> ADD > AI ER SQUIBB AND SONS 100,000 UNITS/GM; 0.12M

> ADD > AI MYCLOG-32

> ADD > CREAM; TOPICAL

> ADD > NYSTALIN; TRIACETINOLONE ACETONIDE (PAGE 3-141)

AA QUANTUM PHARMICS 500,000 UNITS

TABLET; ORAL

AA PHARMAFAIR 100,000 UNITS/ML

AA BAY LABORATORIES 100,000 UNITS/ML

SUSPENSION; ORAL

NYSTALIN (PAGE 3-141)

/N.17518/

PHENTERMINE HYDROCHLORIDE (PAGE 3-151)

> ADD > AA CHELSEA LABORATORIES 30MG

> ADD > AA VITAMINE/PHOENIX 30MG

> ADD > AA DRUGHER/PHOENIX 30MG

TABLET; ORAL

> ADD > AA VITAMINE/PHOENIX 30MG

> ADD > AA VITAMINE/PHOENIX 30MG

> ADD > AA VITAMINE/PHOENIX 30MG

> ADD > AA DRUGHER/PHOENIX 30MG

PHENOXETRAZINE TARTRATE

CAPSULE; ORAL

PHENOXETRAZINE TARTRATE (PAGE 3-149)

TABLET; CONTROLLED RELEASE; ORAL

PENTOXIFYLLINE (PAGE 3-149)

> ADD > AA VITAMINE/PHOENIX 100MG

TABLET; ORAL

> ADD > AA VITAMINE/PHOENIX 100MG

CAPSULE; ORAL

PENTOBARBITAL SODIUM (PAGE 3-149)

PENTOBARBITAL SODIUM (PAGE 3-149)

INJECTABLE; INJECTION

YTERBIUM YB 169 DTPA

MEDICAL PRODUCTS/3M 2MCI/ML

PENTATE CALCIUM TRISODIUM, YB-169 (PAGE 3-140)

PENTAM 300

LYPHOMED

INJECTABLE; INJECTION

PENTAMIDINE ISETHIONATE (PAGE 3-140)

N 86797

N 86740

N 86005

N 85519

N 86106

N 85670

N 85645

N 85634

N 86410

N 86408

N 86403

N 18631

N 83285

N 83284

N 17518

N 19264

PHENTERMINE HYDROCHLORIDE (PAGE 3-151)

TABLET; ORAL
PHENTERMINE HCL
 > ADD > AA 2 DRUGIER/PHOENIX 8MG N 86453
 > ADD > AA 2 8MG N 86456

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-153)

SYRUP; ORAL
PHENERGAN VC
 AA WYETH LABS/AMHO 5MG/5ML;6.25MG/5ML N 08604
PRONETH VC PLAIN
 AA NATL PHARM MFG/BARRE 5MG/5ML;6.25MG/5ML N 88761
PRMETHAZINE VC PLAIN
 AA BAY LABORATORIES 5MG/5ML;6.25MG/5ML N 88897

PHENYTOIN SODIUM (PAGE 3-153)

INJECTABLE; INJECTION
PHENYTOIN SODIUM
 > ADD > AP INVENEX LABS/LIFE 50MG/ML N 89003
 AP SOLOPAK LABORATORIES 50MG/ML N 88519
 AP 50MG/ML N 88520
 AP 50MG/ML N 88521

PHENYTOIN SODIUM, EXTENDED (PAGE 3-153)

CAPSULE; ORAL
DILANTIN
 AB PARKE-DAVIS/W-L 100MG N 84349
EXTENDED PHENYTOIN SODIUM
 AB BOLAR PHARMACEUTICAL 100MG N 88711

PILOCARPINE HYDROCHLORIDE (PAGE 3-154)

GEL; OPHTHALMIC
 PILOPINE HS
 ALCON LABORATORIES 4% N 18796

PINDOLOL (PAGE 3-154)

TABLET; ORAL
 VISKEN
 SANDOZ PHARMS/SANDOZ/15MG/ N 18285/

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE (PAGE 3-155)

POWDER FOR RECONSTITUTION; ORAL
 COLYTE
 EDLAM PREPARATIONS 120GM/PACKET;1.49GM/PACKET;
 3.36GM/PACKET;2.92GM/PACKET;
 11.36GM/PACKET N 18983
 227.1GM/PACKET;2.82GM/PACKET;
 6.36GM/PACKET;5.53GM/PACKET;
 21.5GM/PACKET; N 18983
 360GM/PACKET;4.47GM/PACKET;
 10.08GM/PACKET;8.76GM/PACKET;
 34.08GM/PACKET N 18983

POTASSIUM CHLORIDE (PAGE 3-156)

INJECTABLE; INJECTION
POTASSIUM CHLORIDE IN PLASTIC CONTAINER
 AP INVENEX LABS/LIFE 2MEQ/ML N 88901
 AP 2MEQ/ML N 88908

POTASSIUM CLAVULANATE; TICARCILLIN DISODIUM (PAGE 3-158)

INJECTABLE; INJECTION
 TIMENTIN
 BEECHAM LABS/BEECHAM EQ 100MG ACID/VIAL;
 EQ 3GM BASE/VIAL N 50590
 EQ 200MG ACID/VIAL;
 EQ 3GM BASE/VIAL N 50590

PREDNISOLONE (PAGE 3-159)

TABLET; ORAL
 PREDNISOLONE
 BX SUPERPHARM 5MG N 88892

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM (PAGE 3-160)

OINTMENT; OPHTHALMIC
PREDISULFAIR
 AT PHARMAFAIR 0.5%;10% N 88032
VASOCIDIN
 AT COOPERVISION PHARMS 0.5%;10% N 88791

PREDNISONE (PAGE 3-161)

SOLUTION; ORAL
 PREDNISONE
 ROXANE LABORATORIES 5MG/5ML N 88703
 PREDNISONE INTENSOL
 ROXANE LABORATORIES 5MG/ML N 88810

QUINIDINE SULFATE (PAGE 3-170)

TABLET; ORAL
CIN-QUIN
 /AB/ ROWELL LABORATORIES /200MG/
 /N 88973/
 AB SUPERPHARM 200MG
 N 88973

RANITIDINE HYDROCHLORIDE (PAGE 3-171)

INJECTABLE; INJECTION
 ZANTAC
 GLAXO EQ 25MG BASE/ML
 N 19090

RAUWOLFIA SERPENTINA (PAGE 3-171)

TABLET; ORAL
 RAUVERID
 BP FOREST LABORATORIES 50MG
 /BP/ /ONEAL, JONES & FEIDMAN/ /50MG/
 WOLFIMA
 BP FOREST LABORATORIES 50MG
 BP FOREST LABORATORIES 100MG
 /BP/ /ONEAL, JONES & FEIDMAN/ /50MG/
 /BP/ /ONEAL, JONES & FEIDMAN/ /100MG/
 N 09225
 /N 09225/
 N 09255
 /N 09255/
 N 09255
 /N 09255/
 N 09255
 /N 09255/

RESERPINE (PAGE 3-172)

TABLET; ORAL
 RESERPINE
 BP LEMMON 0.1MG
 BP 0.25MG
 N 89020
 N 89019

RITODRINE HYDROCHLORIDE (PAGE 3-173)

INJECTABLE; INJECTION
 /RITODRINE HCL/
 /AB/ /PULFAR LABS/ /10MG/ML/
 YUTOPAR
 /AB/ ASTRA PHARM PRODS 10MG/ML
 15MG/ML
 N 18580
 N 18580

TABLET; ORAL
 /RITODRINE HCL/
 /AB/ /PULFAR LABS/ /10MG/
 YUTOPAR
 /AB/ ASTRA PHARM PRODS 10MG
 N 18555

SAFFLOWER OIL; SOYBEAN OIL (PAGE 3-174)

INJECTABLE; INJECTION
 LIPOSYN II 10%
 ABBOTT LABORATORIES 5%;5%
 LIPOSYN II 20%
 ABBOTT LABORATORIES 10%;10%
 N 18997
 N 18991

SCOPOLAMINE (PAGE 3-174)

FILM, CONTROLLED RELEASE; PERCUTANEOUS
 /TRANSDERM-V/
 /AB/ /1.5MG/
 TRANSDERM-SCOP
 CIBA/CIBA-GEIGY 1.5MG
 N 17874

SECOBARBITAL SODIUM (PAGE 3-174)

CAPSULE; ORAL
 SECOBARBITAL SODIUM
 3 DRUTHIER/PHOENIX 100MG
 3 VITARINE/PHOENIX 100MG
 N 85898
 N 86273

SODIUM CHLORIDE (PAGE 3-176)

INJECTABLE; INJECTION
 BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
 AP ABBOTT LABORATORIES 9MG/ML N 18800
 AP INVENEX LABS/LIFE 9MG/ML N 88909
 AP 9MG/ML N 88911
 SODIUM CHLORIDE IN PLASTIC CONTAINER
 /AB/ /AM MCGAW/AM HOSP/ /900MG/100ML/
 SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
 AP AM MCGAW/AM HOSP 900MG/100ML N 17464
 AP INVENEX LABS/LIFE 9MG/ML N 88912

SLUSH; IRRIGATION
 SODIUM CHLORIDE 0.9% IN STERILE PLASTIC CONTAINER
 TRAVENOL LABS 900MG/100ML
 N 19319

SODIUM LACTATE (PAGE 3-178)

INJECTABLE; INJECTION
 SODIUM LACTATE IN PLASTIC CONTAINER
 ABBOTT LABORATORIES 5MEQ/ML
 N 18947

SODIUM NITROPRUSSIDE (PAGE 3-178)

INJECTABLE; INJECTION
 SODIUM NITROPRUSSIDE
 AP LYPHOMED 50MG/VIAL
 N 70031

TECHNETIUM, TC-99M, SULFUR COLLOID KIT (PAGE 3-187)

INJECTABLE; INJECTION
/CONTIENEM TECHNETIUM 99M TSO/
/CONTIENEM/
/N/A/
TECHNETIUM TC 99M TSO
AP MEDI-PHYSICS N/A

/N'17784/
N 17784

TERBUTALINE SULFATE (PAGE 3-187)

AEROSOL; INHALATION
BRETHAIRE
BN GEIGY/CIBA-GEIGY 0.2MG/INH
BRICANYL
BN MERRELL DOW/DOW CHEM 0.2MG/INH

N 18762
N 18000

INJECTABLE; INJECTION
BRICANYL
> DLT > /A/ /ASTRA PHARM FRODOB/ /1MG/ML/
> ADD > AP MERRELL DOW/DOW CHEM 1MG/ML

/N'17466/
N 17466

> ADD > TERFENADINE (PAGE 3-187)

> ADD > TABLET; ORAL
> ADD > SELDANE
> ADD > MERRELL DOW/DOW CHEM 60MG

N 18949

TETRACYCLINE HYDROCHLORIDE (PAGE 3-188)

CAPSULE; ORAL
BRISTACLYNE
/A/ BRISTOL LABS/D-M /400MG/
TETRACYCLINE HCL
AB SUPERPHARM 250MG
AB 500MG

/N'62540/
N 62540
N 62540

THEOPHYLLINE (PAGE 3-190)

CAPSULE; ORAL
SOMOPHYLLIN-T
BP FISON 100MG
BP 200MG
BP 250MG

N 87155
N 87155
N 87155

CAPSULE, CONTROLLED RELEASE; ORAL

ELIXOPHYLLIN SR
BC BERLEX/SCHERING 125MG
BC 250MG
SLO-BID
BC WILLIAM H RORER 50MG
BC 100MG
BC 200MG
BC 300MG

N 86826
N 86826
N 88269
N 87892
N 87893
N 87894

THEOPHYLLINE (PAGE 3-190)

CAPSULE, CONTROLLED RELEASE; ORAL

SLO-PHYLLIN
BC WILLIAM H RORER 125MG N 85203
SOMOPHYLLIN-CRT
BC FISON 50MG N 87763
BC 200MG N 88382
BC 300MG N 88383
THEO-24
BC SEARLE/SEARLE PHARMS 200MG N 87943
BC 300MG N 87944
THEOBID
BC GLAXO 260MG N 85983
THEOBID JR.
BC GLAXO 130MG N 87854
THEOCLEAR L.A.-130
BC CENTRAL PHARMS 130MG N 86569
THEOPHYL-SR
BC MCNEIL PHARM 125MG N 86480
BC 250MG N 86471
THEOPHYLLINE
BC CENTRAL PHARMS 125MG N 88654
BC 250MG N 88689
THEOVENT
BC SCHERING 125MG N 87010
BC 250MG N 87910

TABLET, CONTROLLED RELEASE; ORAL

THEOCHEM
BC FOREST LABORATORIES 100MG N 88320
BC 200MG N 88321
THEOPHYLLINE
BC FOREST LABORATORIES 100MG N 88503
BC 200MG N 88504
AB 300MG N 88505

THIORIDAZINE HYDROCHLORIDE (PAGE 3-192)

TABLET; ORAL

THIORIDAZINE HCL
AB BARR LABORATORIES 150MG N 88737
AB 200MG N 88738
AB BIOCRAFT LABS 10MG N 88493
AB 100MG N 88456
AB CORD LABORATORIES 100MG N 88135
AB DANBURY PHARMACAL 200MG N 88872
AB ROXANE LABORATORIES 100MG N 89048

TOBRAMYCIN (PAGE 3-194)

SOLUTION/DROPS; OPHTHALMIC

TOBREX
ALCON LABORATORIES 0.3% N 62535

TRIPROLIDINE HYDROCHLORIDE (PAGE 3-200)

SYRUP; ORAL
TRIPROLIDINE HCL
 AA HALSEY DRUG 1.25MG/5ML N 88735

TRISULFAPYRIMIDINES (PAGE 3-200)

SUSPENSION; ORAL
TRISULF SULFADO
 /AB/ /VALE. CHEMICAL/ /500MG/5ML/ /N. 88167/

VECURONIUM BROMIDE (PAGE 3-202)

INJECTABLE; INJECTION
NORCURON (N.C. 45)
 NORCURON

VERAPAMIL HYDROCHLORIDE (PAGE 3-202)

TABLET; ORAL
CALAN
 AB SEARLE/SEARLE PHARMS 80MG N 18817
 AB 120MG N 18817
ISOPTIN
 AB KNOLL PHARMACEUTICAL 80MG N 18593
 AB 120MG N 18593

VINCRISTINE SULFATE (PAGE 3-202)

INJECTABLE; INJECTION
 ONCOVIN
 > DLT > /ELI. LILLY/ /1MG/AMP/ /N. 14103/
 > DLT > /ELI. LILLY/ /5MG/AMP/ /N. 14103/
 > ADD > ELI LILLY 1MG/ML N 14103

WATER FOR INJECTION, STERILE (PAGE 3-204)

LIQUID; N/A
STERILE WATER FOR INJECTION IN PLASTIC CONTAINER
 > ADD > AP TRAVENOL LABS 100Z N 18632
 > DLT > /AB/ STERILE WATER IN PLASTIC CONTAINER
 /TRAVENOL LABS/ /100Z/ /N. 18632/

[illegible]

/ASCOBIC ACID; DEHPANTHENE; NIACINAMIDE; PYRIDOXINE/
 /HYDROCHLORIDE; RIBOFLAVIN; THIAZINE NITROGLYCERIN; VITAMIN A1/
 /VITAMIN B1 VITAMIN E (PAGE AD3)
 (SEE SPECIAL NOTE B.)

/INJECTABLE; INJECTION/
 /N.Y./

/US; PHARMACEUTICAL/ /50mg/mL; 100mg/mL; 200mg/mL;
 /100mg/mL; 200mg/mL; 400mg/mL; 800mg/mL;
 /0.5mg/mL/ /N 86800/
 /100mg/mL; 200mg/mL; 400mg/mL;
 /100mg/mL; 200mg/mL; 400mg/mL;
 /200, 100mg/mL/ /N 86803/

DIPYRIDAMOLE (PAGE AD4)

TABLET; ORAL

DIPYRIDAMOLE

> ADD >	DANBURY PHARMACAL	25MG	N 88945
> ADD >		50MG	N 88900
> ADD >		75MG	N 87432
> ADD >	PHARM BASICS	50MG	N 88922
	SIDHAK LABORATORIES	25MG	N 88683
		50MG	N 88684
		75MG	N 88685

> ADD >
 > ADD >
 > ADD >

NITROGLYCERIN (PAGE AD7)

/CAPSULE; CONTROLLED RELEASE; ORAL/
 (ALL PRODUCTS - SEE SPECIAL NOTE B.)

/TABLET; CONTROLLED RELEASE; ORAL/
 (ALL PRODUCTS - SEE SPECIAL NOTE B.)

PENTAERYTHRITOL TETRA-NITRATE (PAGE AD8)

CAPSULE, CONTROLLED RELEASE; ORAL

PENTAERYTHRITOL TETRA-NITRATE

2	VITARINE/PHOENIX	80MG
2		80MG
2		80MG

N 86305
 N 87529
 N 87531

/ISOSORBIDE DINITRATE/ (PAGE AD5)

(ALL PRODUCTS - SEE SPECIAL NOTE B.)

/TABLET; ORAL/
 /ISOSORBIDE DINITRATE/
 /BARR LABORATORIES/ /30mg/

/N 87564/

/TABLET; SUBLINGUAL/
 /ISOSORBIDE DINITRATE/
 /BARR LABORATORIES/ /10mg/

/N 87545/

/TABLET; CONTROLLED RELEASE; ORAL/
 /ISOSORBIDE DINITRATE/
 /FOREST LABORATORIES/ /20mg/

/N 88428/

M.V.I. PEDIATRIC USV PHARMACEUTICAL
 ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
 ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE;
 PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM;
 THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E

TUSS-ORNADE SKAF LABORATORIES
 CARAPHEN EDISYLATE; CHLORPHENIRAMINE MALEATE;
 ISOPROPAMIDE IODIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE

/NITRACORT/ /OWEN LABS/DEHN PRODS/
 /HYDROCORTISONE/
 /PHTHICOLINE/ /CIBA/CIBA-GEIGY/
 /DIPLOAZOLINE HYDROCHLORIDE/

BEROCCA C 500 HOFFMANN-LA ROCHE
 ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE
 HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE
 BEROCCA C HOFFMANN-LA ROCHE
 ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE

/BENTON W. PHARMACEUTICAL/ /NEBELT, DON/ DON CHEN/
 /DIPLOAZOLINE HYDROCHLORIDE, PHENYLPROPANOLAMINE/

CURRENT STATUS - INEFFECTIVE

DIMETAPP AH ROBINS
 BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE;
 PHENYLPROPANOLAMINE HYDROCHLORIDE
 /CETACORT/ /OWEN LABS/DEHN PRODS/
 /HYDROCORTISONE/

/MC (HYDROCORTISONE)/ /F. AND N. PHARMACEUTICAL/
 /HYDROCORTISONE/

/HYDROCORTISONE/ /TONE, PAULSEN/
 /HYDROCORTISONE/

/XLOCTIN/ /E.L. LILL/
 /ERYTHROMYCIN/

> DLT > /MYCLOG/ /ER SQUIBB AND SONS/
 > DLT > /GALANTHIN/ /NEOTICIN SULFATES/ /WYSTALIN/

/NEOSTOMIN 6/ /ARMONIA WELLS/
 /BRANICIDIN/ /NEOTICIN SULFATES/ /POLYVONIN E SULFATE/

/TERRA-CORTIL/ /PETER LABS/PETER/
 /HYDROCORTISONE, DEXTETRAACETATE, HCL/

ADDENDUM D: DRUG PRICE COMPETITION AND PATENT TERM RESTORATION

On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984. The Act amends section 505 of the Federal Food, Drug and Cosmetic Act, authorizing the Agency to accept abbreviated new drug applications for most previously approved drug products. This new legislation also provides for extending the term of a patent which claims a product, use, or method of manufacture that was subject to a regulatory review period in accordance with the Act.

The statute requires that FDA make publicly available a list of approved drug products containing the following information:

- 1) an alphabetical list of all drugs by official and proprietary name approved for safety and effectiveness, with monthly updates;
- 2) the application number and approval date for each drug product approved from January 1, 1982; and
- 3) whether in vitro and/or in vivo bioequivalence studies are required for ANDA approval.

The Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 5th Edition, (APDP) and its monthly supplements will be used to satisfy this new requirement.

In addition, the APDP will identify drugs which qualify under the new statute for periods of exclusivity (during which ANDAs and paper NDAs for those drugs may not be submitted or made effective as identified below) and will provide information on the current patent status of the listed drugs. Exclusivity prevents the filing and/or approval of ANDAs or paper NDAs. It does not prevent the filing or approval of a second full NDA. Applications qualifying for periods of exclusivity are:

- (1) A new drug application approved between January 1, 1982, and September 24, 1984, for a drug product all active ingredients (including any ester or salt of the active ingredient) of which had never been approved in any other application. Approval of an ANDA or paper NDA for the same drug may not be made effective for a period of ten years from the date of the approval of the original application.

- (2) A new drug application approved after September 24, 1984, for a drug product all active ingredients (including any ester or salt of the active ingredient) of which had never been approved in any other new drug application. Generally, no subsequent ANDA or paper NDA for the same drug may be submitted for a period of five years from the date of approval of the original application, except that such an application may be submitted after four years if it contains a certification that a patent claiming the drug is invalid or will not be infringed by the product for which approval is sought.
- (3) A new drug application approved after September 24, 1984, for a drug product involving an active ingredient (or any ester or salt of that active ingredient) that has been approved in an earlier new drug application and which includes reports of new clinical investigations (other than bioavailability studies). Such investigations must have been conducted or sponsored by the applicant or for which the applicant had a right of reference, and the investigations must have been essential to approval of the application. If these requirements are met, the approval of a subsequent ANDA or paper NDA may not be made effective for the same drug before the expiration of three years from the date of approval of the original application.
- (4) A supplement to a new drug application approved after September 24, 1984, which contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the applicant or to which the applicant had a right of reference. The approval of a subsequent application for a change approved in the supplement may not be made effective for three years from the date of approval of the original supplement.
- (5) A new drug application (or supplement to a new drug application) approved during the period from January 1, 1982, to September 24, 1984, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application. The approval of a subsequent application for the drug or a significant change made in a supplement may not be made effective for two years from September 24, 1984.

The Act required approved new drug applications to be supplemented with the required patent information by October 24, 1984. Patent information must now be filed with all newly submitted drug applications, and no NDA may be approved after September 24, 1984, without the pertinent patent information. The patent numbers and the expiration dates of any appropriate product or use patent on a marketed drug that is the subject of an approved NDA will be published in the ADP. Patent information on unapproved applications or on patents beyond the scope (i.e., process or manufacturing) of the Act will not be published.

The following explains how the ADP implements this.

Antibiotics, Insulin and Biologicals

Title I of the Act has been interpreted by the Agency not to include products approved under sections 506 or 507 of the Federal Food, Drug and Cosmetic Act (antibiotic and insulin products). Because of this, (1) antibiotic and insulin products are not considered eligible for exclusivity protection, (2) holders of approved applications for insulin and antibiotic products need not submit the patent information as required of NDA application holders, and (3) Antibiotic Form 6 sponsors are not required to provide the patent certification statement which must be included in NDAs.

However, Title II, the patent term restoration portion of the Act, specifically addresses antibiotic, non-antibiotic, and human biological products (as those terms are used in the Federal Food, Drug and Cosmetic and Public Health Service Acts) in its provisions.

Bioavailability/Bioequivalence Requirements

The therapeutic equivalence evaluation codes in the ADP will enable firms to determine whether in vitro and/or in vivo bioavailability/bioequivalence study data must be included with their NDA submissions.

Currently, drugs approved prior to 1962 fall into three major biopharmaceutical classes: (1) those which pose an actual or potential bioequivalence problem, and for which demonstration of bioequivalence through in vivo testing and acceptable dissolution performance is necessary; (2) those which pose an actual or potential bioequivalence problem but for which an in vivo study may be waived if acceptable dissolution performance is demonstrated (the list of such drugs is provided under TABLE I); and (3) those which pose no actual or potential bioequivalence problem and for which the only biopharmaceutical requirement is demonstration of acceptable dissolution for solid oral dosage forms.

All firms submitting an abbreviated new drug application for a single source drug product or a drug product which was first approved after 1962 will be required to demonstrate in vivo bioequivalence or else submit information sufficient to permit the Agency to waive demonstration of in vivo bioequivalence. Manufacturers of drug products formulated in dosage forms which do not present bioequivalence problems, such as an intravenous solution, may request that the in vivo bioequivalence requirement be waived.

Before the passage of the Drug Price Competition and Patent Term Restoration Act, the Agency approved various drugs with bioavailability/bioequivalence problems and deferred the in vivo testing requirement for a number of reasons. The new law requires information to show that the proposed ANDA drug product is bioequivalent to the listed drug. Therefore, new applications for drugs such as amitriptyline hydrochloride which formerly may have been approved without an in vivo study now require an in vivo study as a condition for approval under the new Act.

Topicals

In the absence of contrary data, FDA regarded all pharmaceutically equivalent topical products of pre-1962 (DESI) drugs to be therapeutically equivalent. However, the Agency required that applicants for topical drug products initially approved after 1962, including "paper NDAs," either demonstrate the safety and efficacy of their products through clinical trials or through a bioequivalence study in order to be approved and evaluated as therapeutically equivalent.

The new Act requires applicants to demonstrate the bioequivalence of their topical drug product to the listed drug as one of the requirements for ANDA approval. This is the same policy that is presently being used in the "paper NDA" approval process. The Agency is now reviewing the therapeutic equivalence evaluation policy that has been made on the pre-1962 topical products to determine whether a change in this policy is warranted. In the meantime, an in vivo demonstration of bioequivalence will be required for approval of all topical products unless a waiver or in vitro alternatives can be justified by the applicant.

OTC Drug Products Eligible for Abbreviated New Drug Applications

Previous editions of the APDP excluded OTC drug products, because the main purpose of that publication was to provide information to states regarding FDAs recommendation as to which generic prescription drug products were acceptable candidates for drug product selection. With the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, the Agency now has the responsibility to publish an up-to-date list of all marketed drug products, OTC as well as prescription, that have been approved for safety and efficacy and for which new drug applications are required. There are some drugs for which there are both approved and unapproved OTC drug products in the market place. This situation occurs as a result of the Agency's current OTC compliance policy which allows the marketing of various unapproved OTC drug products pending the effective date of the applicable final OTC monograph. The OTC products included in APDP cumulative supplement TABLE II are limited to those for which approved applications are currently required as a condition of marketing. Appropriate patent numbers, exclusivity information, and expiration dates are also included.

NDA's Approved by the Office of Biological Research and Review Not Previously Published in the APDP

All products accepted and approved under Section 505 of the Act as NDAs by the Office of Biological Research and Review (OBRR) will now be published in the APDP (see TABLE III). The application holder should have submitted relevant patent and exclusivity information as for other NDA drug products. These products will be listed drugs and ANDA applications may be submitted for marketing of drugs from this group. Appropriate patent numbers, exclusivity information, and expiration dates are also included.

Patent and Exclusivity Information

It was originally planned that TABLE IV of Cumulative Supplement 2 to the APDP would contain patent and exclusivity information. Because some firms submitted patent information in excess of that covered by the statute, FDA has reviewed all of the patent information to assure that only appropriate patents are listed. The patents that FDA regards as covered by the statutory provisions for submission of patent information are those that claim the active ingredient or ingredients of the drug product (excluding process patents), or use patents for a particular indication or method of using the product. The Agency has concluded that formulation/composition patents should be added to the List.

A patent that claims a drug (as contrasted with one that claims a use) must refer to an approved drug product. To ensure that only appropriate patents are published, the Agency has an obligation to carefully screen the patent information that is submitted by the NDA holder. Therefore the Agency is asking all holders of approved applications and applicants with pending applications, whether or not they previously submitted information on composition or formulation patents, to submit such information with the following certification: "The undersigned certifies that the drug or formulation or composition of such drug claimed by the following patents is currently approved under section 505 of the Federal Food, Drug and Cosmetic Act." The certification must be signed by the patent holder or by the person responsible for the NDA submission. The Agency intends to publish this additional patent information in its next supplement to the List after the information with the above described certification is received. The Agency will continue its policy of not publishing process or chemical intermediate patents.

The Agency is required by the law to publish all use patents, even if the use has not been approved by the Agency. Therefore, the publication of a use patent in TABLE IV in no way confers Agency approval on or implies that the indication has been approved. TABLE IV contains patent numbers and expiration dates and, for drug products approved after 1981, the date of approval and application number as required by the Act.

Firms submitting ANDAs after September 24, 1984, that certified that no patent information had been filed should amend their applications, if patent information now appears in this list.

TABLES II-IV now identify all drugs which qualify under the new statute for periods of exclusivity. (See pages A-1 & A-2 of the Addendum for an explanation of exclusivity).

FDA has finished reviewing all patent and exclusivity information received initially from interested parties. The Agency believes TABLES II-IV now contain all appropriate patent and exclusivity information that the Agency regards as being covered by the new statute. This table will be updated monthly to include appropriate patent and exclusivity information. The exclusivity information column in TABLES II-IV designates the date on which the exclusivity ends and the basis for the exclusivity through the use of codes as explained on pages A-7 and A-8.

FDA invites comments from all interested parties on whether it has excluded any patent or exclusivity information that should have been included, or included patent or exclusivity information that should have been excluded. Any revisions to the list will be published in subsequent supplements.

DO TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMNS OF TABLES I-IV THE FOLLOWING ABBREVIATIONS HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THIS PAGE FOR AN EXPLANATION OF THE EXCLUSIVITY ABBREVIATIONS FOUND IN THE TABLES.

ABBREVIATIONS

NC	NEW COMBINATION
NCE	NEW CHEMICAL ENTITY
NDF	NEW DOSAGE FORM
NE	NEW ESTER OR SALT OF AN ACTIVE INGREDIENT
NP	NEW PRODUCT
NR	NEW ROUTE
PP	PARENTERAL IN PLASTIC CONTAINER
RTO	PRESCRIPTION TO OTC STATUS CHANGE
NS	NEW STRENGTH
D	NEW DOSING SCHEDULE (SEE REFERENCE, BELOW)
I	NEW INDICATION (SEE REFERENCE, BELOW)

REFERENCES

NEW DOSING SCHEDULE

D-1	ONCE A DAY APPLICATION
D-2	ONCE DAILY DOSING
D-3	SEVEN DAYS/SEVEN DAYS/SEVEN DAYS DOSING SCHEDULE
D-4	SEVEN DAYS/FOURTEEN DAYS DOSING SCHEDULE
D-5	TEN DAYS/ELEVEN DAYS DOSING SCHEDULE
D-6	SEVEN DAYS/NINE DAYS/FIVE DAYS DOSING SCHEDULE
D-7	BID DOSING
D-8	INTRAVENOUS, EPIDURAL AND INTRATHECAL DOSING
D-9	NARCOTIC OVERDOSE IN ADULTS
D-10	NARCOTIC OVERDOSE IN CHILDREN
D-11	POSTOPERATIVE NARCOTIC DEPRESSION IN CHILDREN

1-1	SEVERE HYPERTENSION IN PEDIATRICS AND NON-MALIGNANT HYPERTENSION
1-2	DYSMENORRHEA
1-3	TREATMENT OF TINEA VERSICOLOR
1-4	SYMPTOMATIC GASTROESOPHAGEAL REFLEX
1-5	NEPHROTOMOGRAPHY
1-6	CONTRAST ENHANCEMENT IN CRANIAL COMPUTED TOMOGRAPHY
1-7	VENOGRAPHY OF LOWER EXTREMITIES
1-8	WHOLE-BODY COMPUTED TOMOGRAPHY
1-9	GATED CARDIAC POOL IMAGING
1-10	POST-MYOCARDIAL INFARCTION
1-11	COLORRECTAL SURGERY
1-12	NAUSEA AND VOMITING ASSOCIATED WITH EMETOGENIC CANCER CHEMOTHERAPY
1-13	CISPLATIN INDUCED EMESIS
1-14	DIABETIC GASTROPARESIS
1-15	POST-MYOCARDIAL INFARCTION
1-16	ACROMEGALY
1-17	PITUITARY TUMORS
1-18	POSTMENOPAUSAL OSTEOPOROSIS
1-19	ANTIDOTE FOR ACETAMINOPHEN OVERDOSAGE
1-20	CONGESTIVE HEART FAILURE BID DOSAGE SCHEDULE
1-21	ACUTE OTITIS MEDIA
1-22	EXERCISE INDUCED BRONCHOSPASMS
1-23	MI OR STROKE
1-24	COMBINED USE WITH NICOTINIC ACID TO LOWER CHOLESTEROL LEVEL
1-25	BLASTOMYCOSES DERMATITIDES
1-26	PEDIATRIC SUBARACHNOID VASCULAR
1-27	PETRIELLEDIUM BOYDII INFECTION
1-28	HEREDITARY ANGIOEDEMA
1-29	INTRACORONARY USE
1-30	PEDIATRIC USE
1-31	DIRECT ISOTOPIC CYSTOGRAPHY
1-32	POSTPARTUM HEMORRHAGE
1-33	USE IN METHADONE INDUCED RESPIRATORY DEPRESSION

INDICATIONS

TABLE I. LIST OF DRUG PRODUCTS WHICH MUST DEMONSTRATE IN VIVO
BIOAVAILABILITY ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

ACETAMINOPHEN; ASPIRIN; BUTALBITAL; CAPSULE OR TABLET; ORAL 160-165MG; 160-165MG; 50MG	AMINOPHYLLINE TABLET; ORAL 100MG 200MG	ASPIRIN; MEPROBAMATE TABLET; ORAL 325MG; 200MG
ACETAMINOPHEN; ASPIRIN; BUTALBITAL CAPSULE OR TABLET; ORAL 325MG; 325MG; 50MG	ASPIRIN; BUTALBITAL; CAPSULE OR TABLET; ORAL 325; 50MG 650; 50MG	ASPIRIN; METHOCARBAMOL TABLET; ORAL 325MG; 200MG
ACETAMINOPHEN; ASPIRIN; BUTALBITAL; CAFFEINE CAPSULE OR TABLET; ORAL 160-165MG; 160-165MG; 50MG; 40MG	ASPIRIN; BUTALBITAL, CAFFEINE CAPSULE OR TABLET; ORAL 325MG; 50MG; 40MG; 650MG; 50MG; 40MG;	CHLOROTHIAZIDE TABLET; ORAL 250MG
ACETAMINOPHEN; ASPIRIN; BUTALBITAL; CAFFEINE CAPSULE OR TABLET; ORAL 325MG; 325MG; 50MG; 40MG	ASPIRIN; CAFFEINE; CARISOPRODOL TABLET; ORAL 160MG; 32MG; 200MG	ESTROGENS, CONJUGATED; MEPROBAMATE TABLET; ORAL 0.4MG; 200MG 0.4MG; 400MG
ACETAMINOPHEN; BUTALBITAL CAPSULE OR TABLET; ORAL 325; 50MG 650; 50MG	ASPIRIN; CAFFEINE; CARISOPRODOL; CODEINE PHOSPHATE TABLET; ORAL 160MG; 32MG; 200MG; 16MG	HYDROXYZINE HYDROCHLORIDE TABLET; ORAL 10MG 25MG 50MG 100MG
ACETAMINOPHEN; BUTALBITAL; CAFFEINE CAPSULE OR TABLET; ORAL 325MG; 50MG; 40MG 650MG; 50MG; 40MG	ASPIRIN; CARISOPRODOL TABLET; ORAL 325MG; 200MG	
	ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE 325MG; 200MG; 10MG	

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TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
ACETAMINOPHEN 120MG	NEOPAP (SUPPOSITORY; RECTAL)	WEBCON PHARMS/ALCON	16-401 11-07-68		
ACETAMINOPHEN 650MG	TYLENOL (SUPPOSITORY; RECTAL)	MCNEIL LABORATORIES	17-756 05-26-76		
ACETAMINOPHEN 120MG	TYLENOL (SUPPOSITORY; RECTAL)	MCNEIL LABORATORIES	17-756 05-26-76		
ACETAMINOPHEN 120MG	ACEPHEN (SUPPOSITORY; RECTAL)	G AND W LABORATORIES	18-060 02-09-78		
ACETAMINOPHEN 650MG	ACEPHEN (SUPPOSITORY; RECTAL)	G AND W LABORATORIES	18-060 02-09-78		
ACETAMINOPHEN 650MG	ACETAMINOPHEN (SUPPOSITORY; RECTAL)	UPSHER-SMITH LABS	18-337 04-22-80		
ACETAMINOPHEN 120MG	ACETAMINOPHEN (SUPPOSITORY; RECTAL)	UPSHER-SMITH LABS	18-337 09-12-83		
ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE 80MG; 20MG	GAVISCON (TABLET, CHEWABLE; ORAL)	MARION LABORATORIES	18-685 12-09-83		NP 09-24-86
ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE 160MG; 40MG	GAVISCON-2 (TABLET, CHEWABLE; ORAL)	MARION LABORATORIES	18-685 12-09-83		NP 09-24-86
BROMPHENIRAMINE MALEATE 8MG	DIMETANE (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	10-799 06-10-83		RT0 09-24-86
BROMPHENIRAMINE MALEATE 12MG	DIMETANE (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	10-799 06-10-83		RT0 09-24-86
BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	DIMETAPP (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	12-436 04-02-84		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
CHLORHEXIDINE GLUCONATE	0.5%	HIBITANE	(TINCTURE; TOPICAL)	ICI AMERICAS	18-049	12-18-78			
CHLORHEXIDINE GLUCONATE	0.5%	HIBISTAT	(SOLUTION; TOPICAL)	ICI AMERICAS	18-300	05-23-80			
CHLORHEXIDINE GLUCONATE	4%	EXIDINE	(SOLUTION; TOPICAL)	XTRITIUM LABS	19-125	12-24-84			
CHLORHEXIDINE GLUCONATE	4%	EXIDINE	(AEROSOL; TOPICAL)	XTRITIUM LABS	19-127	12-24-84			
CHLORHEXIDINE GLUCONATE	4%	HIBICLEN	(SOLUTION; TOPICAL)	ICI AMERICAS	17-768	09-17-76			
CHLORHEXIDINE GLUCONATE	4%	HIBICLEN	(SPONGE; TOPICAL)	ICI AMERICAS	18-423	08-27-81			
CHLORPHENIRAMINE MALEATE	8MG	TELORIN	(CAPSULE; CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	17-369	05-11-78			
CHLORPHENIRAMINE MALEATE	12MG	TELORIN	(CAPSULE; CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	17-369	05-11-78			
CHLORPHENIRAMINE MALEATE	8MG	CHLOR-TRIMETON	(TABLET; CONTROLLED RELEASE; ORAL)	SCHERING	07-638	10-18-78			
CHLORPHENIRAMINE MALEATE	12MG	CHLOR-TRIMETON	(TABLET; CONTROLLED RELEASE; ORAL)	SCHERING	07-638	10-18-78			
CHLORPHENIRAMINE MALEATE	4MG; 25MG	DEPMIZIN	(TABLET; CONTROLLED RELEASE; ORAL)	SCHERING	18-556	05-14-84			NS
CHLORPHENIRAMINE MALEATE	8MG; 75MG	CONTAC	(CAPSULE; CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	18-099	02-04-80			

TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 8MG; 75MG	COLD CAPSULE V (CAPSULE, CONTROLLED RELEASE; ORAL)	DM GRAHAM LABS	18-794 04-23-85		
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 8MG; 75MG	PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE (CAPSULE, CONTROLLED RELEASE; ORAL)	CENTRAL PHARMS	18-809 05-07-84		
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	TRIAMINIC-12 (TABLET, CONTROLLED RELEASE; ORAL)	DORSEY LABS/SANDOZ	18-115 07-23-81		
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	COLD CAPSULE IV (CAPSULE, CONTROLLED RELEASE; ORAL)	DM GRAHAM LABS	18-793 04-25-85		
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 8MG; 120MG	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-397 03-31-81		
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE 8MG; 120MG	PSEUDOEPHEDRINE HCL/ CHLORPHENIRAMINE MALEATE (CAPSULE, CONTROLLED RELEASE; ORAL)	DM GRAHAM LABS	18-844 03-20-85		
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE 12MG; 120MG	PSEUDOEPHEDRINE HCL/ CHLORPHENIRAMINE MALEATE (CAPSULE, CONTROLLED RELEASE; ORAL)	DM GRAHAM LABS	18-843 03-18-85		
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE 12MG; 120MG	CODIMAL-L.A. 12 (CAPSULE, CONTROLLED RELEASE; ORAL)	CENTRAL PHARMS	18-935 04-15-85		

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
CHLORPHENIRAMINE POLISTIREX; EQ 4MG MALEATE/5ML; EQ 37.5MG HCL/5ML	CORSYM (SYRUP; ORAL)	PENNMALL PHARM	18-050	01-04-84	4221778	09-09-97	NDF
DEXBROMPHENIRAMINE MALEATE; PSEUDOPHEDRINE SULFATE 2MG; 60MG	DISOPHROL (TABLET; ORAL)	SCHERING	12-394	06-03-60			RTO
DEXBROMPHENIRAMINE MALEATE; PSEUDOPHEDRINE SULFATE 6MG; 120MG	DRIXORAL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	13-483	09-13-82			RTO
DEXBROMPHENIRAMINE MALEATE; PSEUDOPHEDRINE SULFATE 6MG; 120MG	DISOPHROL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	13-483	09-13-82			RTO
DEXBROMPHENIRAMINE MALEATE; PSEUDOPHEDRINE SULFATE 6MG; 120MG	DISOPHROL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	13-483	09-13-82			RTO
DEXBROMPHENIRAMINE MALEATE; PSEUDOPHEDRINE SULFATE EQ 30MG HBR/5ML	DELSYM (SUSPENSION, CONTROLLED RELEASE; ORAL)	PENNMALL PHARM	18-658	10-08-82	4221778	09-09-97	NDF
DIPHENHYDRAMINE HYDROCHLORIDE 12.5MG/5ML	BENYLIN (SYRUP; ORAL)	PARKER-DAVIS/W-L	06-514	08-07-81			
DOXYLAMINE SUCCINATE 25MG	UNISOM (TABLET; ORAL)	Pfizer	18-066	10-06-78			
IBUPROFEN 200MG	ADVIL (TABLET; ORAL)	WHITEHALL LABS/AMHO	18-989	05-18-84	3385886	09-28-85	NS
IBUPROFEN 200MG	NUPRIN (TABLET; ORAL)	UPJOHN MANUFACTURING	19-012	05-18-84	3385886	09-28-85	NS
INSULIN SUSPENSION, ISOPHANE, BEEF 40 UNITS/ML	SEMILENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-929	02-08-77			
INSULIN SUSPENSION, ISOPHANE, BEEF 100 UNITS/ML	SEMILENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-929	02-08-77			

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
INSULIN SUSPENSION, ISOPHANE, BIOSYNTHETIC HUMAN 100 UNITS/ML	HUMULIN N (INJECTABLE; INJECTION)	ELI LILLY	18-781 10-28-82		
INSULIN SUSPENSION, ISOPHANE, MIXED BEEF AND PORK 40 UNITS/ML	NPH ILETIN I (BEEF-PORK) (INJECTABLE; INJECTION)	LILLY RES LABS DIV	17-936 02-08-77		
INSULIN SUSPENSION, ISOPHANE, MIXED BEEF AND PORK 100 UNITS/ML	NPH ILETIN I (BEEF-PORK) (INJECTABLE; INJECTION)	LILLY RES LABS DIV	17-936 02-08-77		
INSULIN SUSPENSION, ISOPHANE, PURIFIED BEEF 100 UNITS/ML	NPH ILETIN II (INJECTABLE; INJECTION)	ELI LILLY	18-479 06-12-80		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK 100 UNITS/ML	INSULIN INSULATARD NPH NORDISK (INJECTABLE; INJECTION)	NORDISK	18-194 01-16-80		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK 100 UNITS/ML	NPH ILETIN II (PORK) (INJECTABLE; INJECTION)	ELI LILLY	18-345 12-05-79		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK 100 UNITS/ML	NPH PURIFIED PORK ISOPHANE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-623 07-30-81		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK; INSULIN, PURIFIED PORK 100 UNITS/ML	INSULIN NORDISK MIXTARD (PORK) (INJECTABLE; INJECTION)	NORDISK	18-195 01-16-80		
INSULIN SUSPENSION, PROTAMINE ZINC, MIXED BEEF AND PORK; 40 UNITS/ML	PROTAMINE, ZINC & ILETIN I (BEEF-PORK) (INJECTABLE; INJECTION)	ELI LILLY	17-932 02-08-77		
INSULIN SUSPENSION, PROTAMINE ZINC, MIXED BEEF AND PORK 100 UNITS/ML	PROTAMINE, ZINC & ILETIN I (BEEF-PORK) (INJECTABLE; INJECTION)	ELI LILLY	17-932 02-08-77		

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF 40 UNITS/ML	PROTAMINE ZINC INSULIN	(INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-928	02-08-77			
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF 100 UNITS/ML	PROTAMINE ZINC INSULIN	(INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-928	02-08-77			
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF; INSULIN, ILETIN II	PROTAMINE ZINC AND ILETIN II	(INJECTABLE; INJECTION)	ELI LILLY	18-476	06-12-80			
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF; INSULIN, ILETIN II (PORK)	PROTAMINE ZINC AND ILETIN II (PORK)	(INJECTABLE; INJECTION)	ELI LILLY	18-346	12-05-79			
INSULIN SUSPENSION, BEEF 40 UNITS/ML	LENTE INSULIN	(INJECTABLE; INJECTION)	SQUIBB-NOVO	17-996	02-08-77			
INSULIN ZINC SUSPENSION, BEEF 100 UNITS/ML	LENTE INSULIN	(INJECTABLE; INJECTION)	SQUIBB-NOVO	17-996	02-08-77			
INSULIN ZINC SUSPENSION, SEMISYNTHETIC PURIFIED HUMAN 100 UNITS/ML	NOVOLIN I	(INJECTABLE; INJECTION)	SQUIBB-NOVO	18-777	08-30-83			
INSULIN ZINC SUSPENSION, EXTENDED, PURIFIED BEEF 100 UNITS/ML	ULTRALENTE	(INJECTABLE; INJECTION)	SQUIBB-NOVO	18-385	03-17-80			
INSULIN ZINC SUSPENSION, EXTENDED, PURIFIED BEEF 100 UNITS/ML	ULTRALENTE INSULIN	(INJECTABLE; INJECTION)	SQUIBB-NOVO	17-997	02-08-77			
INSULIN ZINC SUSPENSION, PROMPT, SEMILENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO			17-996	02-08-77			

TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
INSULIN ZINC SUSPENSION, PROMPT, PURIFIED PORK 100 UNITS/ML	SEMILENTE (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-382 03-17-80		
INSULIN ZINC SUSPENSION, PURIFIED BEEF 100 UNITS/ML	LENTE ILETIN II (INJECTABLE; INJECTION)	ELI LILLY	18-477 06-12-80		
INSULIN ZINC SUSPENSION, PURIFIED BEEF AND PORK 100 UNITS/ML	LENTARD (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-384 03-17-80		
INSULIN ZINC SUSPENSION, PURIFIED PORK 100 UNITS/ML	LENTE ILETIN II (PORK) (INJECTABLE; INJECTION)	ELI LILLY	18-347 12-05-79		
INSULIN ZINC SUSPENSION, PURIFIED PORK 100 UNITS/ML	LENTE (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-383 03-17-80		
INSULIN, SEMISYNTHETIC PURIFIED HUMAN 100 UNITS/ML	NOVOLIN R (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-778 08-30-83		
INSULIN, BIOSYNTHETIC HUMAN 100 UNITS/ML	HUMULIN R (INJECTABLE; INJECTION)	ELI LILLY	18-780 10-28-82		
INSULIN, PORK 40 UNITS/ML	INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-926 02-08-77		
INSULIN, PORK 100 UNITS/ML	INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-926 02-08-77		
INSULIN, PURIFIED BEEF 100 UNITS/ML	REGULAR ILETIN II (INJECTABLE; INJECTION)	ELI LILLY	18-478 06-12-80		
INSULIN, PURIFIED PORK 100 UNITS/ML	INSULIN NORDISK QUICK (PORK) (INJECTABLE; INJECTION)	NORDISK INSULIN LABS	18-193 01-16-80		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	DOSEAGE FORM; ROUTE	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY	EXP. DATE
INSULIN, PURIFIED PORK	100 UNITS/ML	REGULAR Iletin II (PORK)	(INJECTABLE; INJECTION)	ELI LILLY	18-344	12-05-79	SQUIBB-NOVO	18-381	03-17-80	19-065
INSULIN, PURIFIED PORK	100 UNITS/ML	PORK INSULIN	(INJECTABLE; INJECTION)	SQUIBB-NOVO	18-381	03-17-80	SQUIBB-NOVO	19-065	01-23-85	19-065
INSULIN SUSPENSION, ISOPHANE, SEMISYNTHETIC, PURIFIED HUMAN	100 UNITS/ML	NOVOLIN N	(INJECTABLE; INJECTION)	SQUIBB-NOVO	19-065	01-23-85	SQUIBB-NOVO	19-065	01-23-85	19-065
NONOXNYOL-9	1GM	TODAY	(SPONGE; VAGINAL)	VLI CORPORATION	18-683	04-01-83	WALLACE LABS/C-M	18-307	11-09-79	18-551
POTASSIUM IODIDE	130MG	THYRO-BLOCK	(TABLET; ORAL)	WALLACE LABS/C-M	18-307	11-09-79	ROXANE LABORATORIES	18-551	02-19-82	18-664
POTASSIUM IODIDE	1GM/ML	POTASSIUM IODIDE	(SOLUTION; ORAL)	ROXANE LABORATORIES	18-551	02-19-82	AMGEN	18-664	10-14-82	17-941
PSEUDOPHEDRINE HYDROCHLORIDE	120MG	SUDAFED S.A. (CAPSULE, CONTROLLED RELEASE; ORAL)		BURROUGHS WELLCOME	01-15-79	17-941	BURROUGHS WELLCOME	17-936	11-26-82	19-208
PSEUDOPHEDRINE HYDROCHLORIDE	30MG/5ML; 1.25MG/5ML	ACTIFED (SYRUP; ORAL)		BURROUGHS WELLCOME	17-935	11-26-82	BURROUGHS WELLCOME	17-936	11-26-82	19-208
PSEUDOPHEDRINE HYDROCHLORIDE	60MG; 2.5MG	ACTIFED (TABLET; ORAL)		BURROUGHS WELLCOME	17-936	11-26-82	BURROUGHS WELLCOME	17-936	11-26-82	19-208
PSEUDOPHEDRINE HYDROCHLORIDE	60MG; 2.5MG	ACTIFED (TABLET; ORAL)		BURROUGHS WELLCOME	17-936	11-26-82	BURROUGHS WELLCOME	17-936	11-26-82	19-208

TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	ALLERBAN PLUS (SYRUP; ORAL)	BAY LABORATORIES	88-116 03-04-83		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRI-SUDO (TABLET; ORAL)	MD PHARMACEUTICAL	85-024 01-10-84		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPODRINE (TABLET; ORAL)	DANBURY PHARMACAL	88-112 01-20-83		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	TRIOFED (SYRUP; ORAL)	NATL PHARM MFG/BARRE	88-115 03-04-83		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	TRIPOSED (SYRUP; ORAL)	HALSEY DRUG	88-213 03-30-84		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL (TABLET; ORAL)	CHELSEA LABORATORIES	88-118 01-26-84		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPOSED (TABLET; ORAL)	HALSEY DRUG	88-192 05-01-84		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPROLIDINE AND PSEUDOEPHEDRINE (TABLET; ORAL)	BOLAR PHARMACEUTICAL	88-318 01-13-84		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	TRIPOSED (SYRUP; ORAL)	HALSEY DRUG	88-213 05-01-84		RT0 09-24-86
PSEUDOEPHEDRINE SULFATE 120MG	AFRINOL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-191 10-30-80		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
TRIPROLOLINE HYDROCHLORIDE	1%	TRIOCONAZOLE	TRIOSYD (CREAM; TOPICAL)	Pfizer Cen Res/Pfizer	18-682	02-18-83	12-13-94	02-18-93	NCE
TRIPROLOLINE HYDROCHLORIDE	2.5MG	ACTIDIL	(TABLET; ORAL)	BURROUGHS WELLCOME	11-110	04-14-58		09-24-86	RTO
TRIPROLOLINE HYDROCHLORIDE	2.5MG	TRIPROLOLINE HCL	(TABLET; ORAL)	BOLAR PHARMACEUTICAL	84-453	02-06-76		09-24-86	RTO
TRIPROLOLINE HYDROCHLORIDE	2.5MG	TRIPROLOLINE HCL	(TABLET; ORAL)	DANBURY PHARMACAL	85-094	02-07-77		09-24-86	RTO
TRIPROLOLINE HYDROCHLORIDE	2.5MG	TRIPROLOLINE HCL	(TABLET; ORAL)	DRUMMER/PHOENIX	85-610	03-21-78		09-24-86	RTO
TRIPROLOLINE HYDROCHLORIDE	1.25MG/5ML	ACTIDIL	(SYRUP; ORAL)	BURROUGHS WELLCOME	11-496	07-24-58		09-24-86	RTO
TRIPROLOLINE HYDROCHLORIDE	1.25MG/5ML	BAYDYL	(SYRUP; ORAL)	BAY LABORATORIES	87-963	01-18-83		09-24-86	RTO
TRIPROLOLINE HYDROCHLORIDE	1.25MG/5ML	TRIPROLOLINE HCL	(SYRUP; ORAL)	NATL PHARM MFG/BARRR	85-940	07-13-79		09-24-86	RTO
TRIPROLOLINE HYDROCHLORIDE	1.25MG/5ML	TRIPROLOLINE HCL	(SYRUP; ORAL)	PHARMS ASSOC/BEACH	87-514	02-10-82		09-24-86	RTO

TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

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TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO. APPROVAL DATE	PATENT NO. EXP. DATE	EXCLUSIVITY EXP. DATE
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	10-102 12-14-61		
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	11-912 9-2-59		
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	10-855 06-11-59		
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	16-918 3-17-78		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE-1 SOLUTION	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	80-77 11-6-80		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION	NONE (INJECTABLE; INJECTION)	DELMED	78-519 4-23-80		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION	NONE (INJECTABLE; INJECTION)	TERUMO AMERICA	82-528 11-3-82		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	77-420 5-12-78		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	16-527 6-22-70		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	80-222 8-23-82		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	16-907 5-15-73		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TERUMO AMERICA	78-1211 6-10-81		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	17-401 12-6-77		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	81-1012 6-28-83		

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TABLE III: FDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

ACTIVE INGREDIENT(S)	TRADE NAME	DOSEAGE FORM: ROUTE	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
ANTI-ICHAAGULANT CITRATE PHOSPHATE DEXTROROSE SOLUTION USP WITH: SODIUM CHLORIDE USP 0.9GM/100ML, MANNITOL USP 0.75GM/100ML, ADENINE 0.27GM/100ML	ADSOR [®] RED CELL PRESERVATION SOLUTION (INJECTABLE; INJECTION)		TRAVENOL LABS	81-1104	5-16-83			
ANTI-ICHAAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION WITH: AS-2: CITRIC ACID USP 0.42GM/100ML, DIBASIC SODIUM PHOSPHATE USP 0.285GM/100ML, SODIUM CHLORIDE USP 0.718 GM/100ML, ADENINE 0.017GM/100ML, DEXTROROSE USP 0.396GM/100ML, SODIUM CITRATE USP 0.588GM/100ML	AS-2 NUTRICEL ADITIVE SYSTEM	(INJECTABLE; INJECTION)	CUTTER BIOL/MILES	82-915	9-22-83			
ANTI-ICHAAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION WITH: AS-3: CITRIC ACID USP 0.042 GM/100ML, MONOBASIC SODIUM PHOSPHATE USP 0.276GM/100ML, SODIUM CHLORIDE USP 0.410 GM/100ML, ADENINE 0.30 GM/100ML, DEXTROSE USP 1.10 GM/100ML, SODIUM CITRATE USP 0.588GM/100ML	AS-3 NUTRICEL ADITIVE SYSTEM	(INJECTABLE; INJECTION)	CUTTER BIOL/MILES	82-915	10-19-84			
ANTI-ICHAAGULANT HEPARIN SOLUTION USP	NONE	(INJECTABLE; INJECTION)	DELMED	77-822	5-17-78			
ANTI-ICHAAGULANT HEPARIN SOLUTION USP	NONE	(INJECTABLE; INJECTION)	TRAVENOL LABS	81-1217	5-16-83			
ANTI-ICHAAGULANT SODIUM CITRATE SOLUTION USP	NONE	(INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	81-416	10-12-83			
ANTI-ICHAAGULANT SODIUM CITRATE SOLUTION USP	NONE	(INJECTABLE; INJECTION)	CUTTER BIOL/MILES	76-305	6-30-78			
ANTI-ICHAAGULANT SODIUM CITRATE SOLUTION USP	NONE	(INJECTABLE; INJECTION)	DELMED	16-702	12-28-70			
ANTI-ICHAAGULANT SODIUM CITRATE SOLUTION USP	NONE	(INJECTABLE; INJECTION)	TERUMO AMERICA	78-1214	2-8-80			
ANTI-ICHAAGULANT SODIUM CITRATE SOLUTION USP	NONE	(INJECTABLE; INJECTION)	TRAVENOL LABS	77-923	1-20-78			

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TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO. APPROVAL DATE	PATENT NO. EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	16-375 7-25-67		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	16-375 7-25-67		
DEXTRAN 75, 6% 6GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	8-819 3-31-53		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	8-819 3-31-53		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-253 2-4-83		
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	AMERICAN MCGAW	16-767 4-6-70		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	AMERICAN MCGAW	16-767 4-6-70		
DEXTRAN 70, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	AMERICAN MCGAW	9-024 8-18-69		
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	16-653 9-23-69		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	16-653 9-23-69		

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DEXTRAN 70, 6% SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE	CUTTER BIOL/MILES	8-716	8-11-69			
DEXTRAN 40, 10% SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE	PHARMACHEN	16-836	11-14-70			
DEXTRAN 40, 10% DEXTROSE 5% 10GM/100ML IN 5GM/100ML	NONE	PHARMACHEN	16-836	11-14-70			
DEXTRAN 75, 6% SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE	PHARMACHEN	8-564	9-19-52			
DEXTRAN 75, 6% SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE	PHARMACHEN	16-759	8-19-70			
DEXTRAN 1 150MG/ML IN 6MG/ML	PROMIT	PHARMACIA LABS	83-715	10-30-64			
DEXTRAN 40, 10% RHEOMACRODEX [®] 10GM/100ML IN 5GM/100ML	RHEOMACRODEX [®]	PHARMACIA LABS	14-716	1-18-67			
DEXTRAN 40, 10% RHEOMACRODEX [®] 10GM/100ML IN 5GM/100ML	RHEOMACRODEX [®]	PHARMACIA LABS	14-716	1-18-67			
DEXTRAN 70, 6% DEXTROSE 5% 6GM/100ML IN 5GM/100ML	MACRODEX [®]	PHARMACIA LABS	6-826	6-8-54			
DEXTRAN 70, 6% SODIUM CHLORIDE 0.9% 0.9GM/100ML	MACRODEX [®]	PHARMACIA LABS	6-826	6-8-54			

TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO. APPROVAL DATE	PATENT NO. EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	GENTRAN ^R 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-628 11-4-68		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	GENTRAN ^R 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-628 11-4-68		
DEXTRAN 40, 10% 10GM/100ML DEXTROSE 5% 5GM/100ML	GENTRAN ^R 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	84-619 2-22-85		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	GENTRAN ^R 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	84-620 2-22-85		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	GENTRAN ^R 75 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-607 1-26-70		
DEXTRAN 75, 6% INVERTED SUGAR 10% 6GM/100ML; 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	6% GENTRAN ^R 75 AND 10% TRAVER ^R (INJECTABLE; INJECTION)	TRAVENOL LABS	8-788 2-9-53		
HETASTARCH, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	HESPAN ^R (INJECTABLE; INJECTION)	AM CRITICAL CARE	16-889 7-17-72	3523938 8-11-87	
PROPIOLACTONE 99% 99GM/100ML	BETAPRONE (SOLUTION; CHEMICAL STERILIZING AGENT)	ONEAL JONES&FELDMAN	11-657 9-11-59		
UROKINASE 5000 IU/VIAL	ABBOKINASE OPEN-CATHETER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	76-1021 12-15-83		NS 09-24-86
UROKINASE 250,000 IU/VIAL	ABBOKINASE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	76-1021 7-31-78		I-29 09-24-86
UROKINASE 250,000 IU/VIAL	BREOKINASE (INJECTABLE; INJECTION)	STERLING DRUG	17-873 8-28-79		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
ACEBUTOLOL HYDROCHLORIDE EQ 200MG BASE	SECTRAL (CAPSULE; ORAL)	IVES LABS/AMHO	18-917 12-28-84	3726919 04-10-90 3857952 12-31-91	NCE 12-28-89
ACEBUTOLOL HYDROCHLORIDE EQ 400MG BASE	SECTRAL (CAPSULE; ORAL)	IVES LABS/AMHO	18-917 12-28-84	3726919 04-10-90 3857952 12-31-91	NCE 12-28-89
ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE 650MG; EQ 25MG BASE	TALACEN (TABLET; ORAL)	STERLING DRUG	18-458 09-23-82	4105659 08-08-95	NC 09-24-86
ACETIC ACID, GLACIAL 250MG/100ML	ACETIC ACID 0.25% IN PLASTIC CONTAINER (SOLUTION; URETHRAL)	TRAVENOL LABS	18-523 02-19-82		
ACETOHYDROXAMIC ACID 250MG	LITHOSTAT (TABLET; ORAL)	URO-RESEARCH	18-749 05-31-83		NCE 05-31-93
ACYCLOVIR 5%	ZOVIRAX (OINTMENT; TOPICAL)	BURROUGHS WELLCOME	18-604 03-29-82	4199574 04-22-97	NCE 03-29-92
ACYCLOVIR 200MG	ZOVIRAX (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-828 01-25-85	4199574 04-22-97	NCE 03-29-92
ACYCLOVIR SODIUM EQ 500MG BASE/VIAL	ZOVIRAX (INJECTABLE; INJECTION)	BURROUGHS WELLCOME	18-603 10-22-82	4199574 04-22-97	NCE 03-29-92
ALBUTEROL 0.09MG/INH	PROVENTIL (AEROSOL; INHALATION)	SCHERING	17-559 05-01-81	3644353 02-22-89 3705233 12-05-89	I-22 09-24-86
ALBUTEROL 0.09MG/INH	VENTOLIN (AEROSOL; INHALATION)	GLAXO	18-473 05-01-81	3644353 02-22-89 3705233 12-05-89	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	DOOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
ALBUTEROL SULFATE	EQ 2MG BASE	PROVENTIL	(TABLET; ORAL)	SCHERING	17-853	02-22-89	3644353	09-24-86	NE
ALBUTEROL SULFATE	EQ 4MG BASE	PROVENTIL	(TABLET; ORAL)	SCHERING	17-853	05-07-82	3644353	09-24-86	NE
ALBUTEROL SULFATE	EQ 2MG BASE/SML	PROVENTIL	(SYRUP; ORAL)	SCHERING	18-062	01-19-83	3644353	12-05-89	
ALCLOMETASONE DIPROPIONATE	0.05%	VADERM	(OINTMENT; TOPICAL)	SCHERING	18-702	12-14-82	4124707	12-14-92	NCE
ALCLOMETASONE DIPROPIONATE	0.05%	VADERM	(CREAM; TOPICAL)	SCHERING	18-707	12-14-82	4124707	12-14-92	NCE
ALLOPURINOL	100MG	ALLOPURINOL	(TABLET; ORAL)	BOLAR PHARMACEUTICAL	18-241	11-16-84			
ALLOPURINOL	300MG	ALLOPURINOL	(TABLET; ORAL)	BOLAR PHARMACEUTICAL	18-241	11-16-84			
ALLOPURINOL	100MG	ALLOPURINOL	(TABLET; ORAL)	CHELSEA LABORATORIES	18-785	09-28-84			
ALLOPURINOL	300MG	ALLOPURINOL	(TABLET; ORAL)	CHELSEA LABORATORIES	18-785	09-28-84			
ALLOPURINOL	100MG	ALLOPURINOL	(TABLET; ORAL)	DANBURY PHARMACAL	18-832	09-28-84			
ALLOPURINOL	300MG	ALLOPURINOL	(TABLET; ORAL)	DANBURY PHARMACAL	18-877	09-28-84			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
ALLOPURINOL 100MG	ZYLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	16-084 08-19-66	3624205 11-30-88	
ALLOPURINOL 300MG	ZYLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	16-084 01-14-74	3624205 11-30-88	
ALLOPURINOL 100MG	LOPURIN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-297 06-10-80	3624205 11-30-88	
ALLOPURINOL 300MG	LOPURIN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-297 06-10-80	3624205 11-30-88	
ALPRAZOLAM 0.25MG	XANAX (TABLET; ORAL)	UPJOHN	18-276 10-16-81	3987052 10-19-93 3980789 09-14-93	
ALPRAZOLAM 0.5MG	XANAX (TABLET; ORAL)	UPJOHN	18-276 10-16-81	3987052 10-19-93 3980789 09-14-93	
ALPRAZOLAM 1MG	XANAX (TABLET; ORAL)	UPJOHN	18-276 10-16-81	3987052 10-19-93 3980789 09-14-93	
AMCINONIDE 0.1%	CYCLOCORT (CREAM; TOPICAL)	LEDERLE LABS/AM CYAN	18-116 10-18-71	4158055 06-12-96	
AMCINONIDE 0.1%	CYCLOCORT (OINTMENT; TOPICAL)	LEDERLE LABS/AM CYAN	18-498 11-13-81	4158055 06-12-96	
AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE 5MG; 50MG	MODURETIC 5/50 (TABLET; ORAL)	MS&D/MERCK	18-201 10-05-81	3781430 12-25-90	
AMINO ACIDS 6.9%	FREAMINE HBC 6.9% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	16-822 05-17-83		NS 09-24-86

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
AMINO ACIDS	6.5%	RENAMIN W/O ELECTROLYTES	(INJECTABLE; INJECTION)	TRAVENOL LABS	17-493	10-15-82		09-24-86	NS
AMINO ACIDS	8.5%	NOVAMINE 8.5%	(INJECTABLE; INJECTION)	CUTTER LABS/MILES	17-957	08-09-82			
AMINO ACIDS	11.4%	NOVAMINE 11.4%	(INJECTABLE; INJECTION)	CUTTER LABS/MILES	17-957	08-09-82			
AMINO ACIDS	8%	HEPATAMINE 8%	(INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-676	08-03-82	04-13-93	09-24-86	NS
AMINO ACIDS	4%	BRANCHAMIN 4%	(INJECTABLE; INJECTION)	TRAVENOL LABS	18-678	09-28-84	4438144	09-24-86	NS
AMINO ACIDS	4%	BRANCHAMIN 4%	(INJECTABLE; INJECTION)	TRAVENOL LABS	18-684	09-28-84	4438144	09-24-86	NS
AMINO ACIDS	6.5%	NEOPHAM 6.5%	(INJECTABLE; INJECTION)	CUTTER-VITRUM	18-792	01-17-84		09-24-86	NS
AMINO ACIDS	3.5%	AMINOSYN 3.5%	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-804	05-15-84		09-24-86	NS
AMINO ACIDS	3.5%	AMINOSYN 3.5%	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-875	08-08-84		09-24-86	NS
AMINO ACIDS	5.2%	AMINOSYN 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE	(INJECTABLE; INJECTION)	CUTTER-VITRUM	18-901	04-06-84			
AMINO ACIDS	5.5%	TRAVASOL 5.5% W/O ELECTROLYTES	(INJECTABLE; INJECTION)	TRAVENOL LABS	18-931	08-23-84		09-24-86	NS

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
AMINO ACIDS 8.5%	TRAVASOL 8.5% W/O ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-931 08-23-84		
AMINO ACIDS 10%	TRAVASOL 10% W/O ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-931 08-23-84		
AMINO ACIDS 6%	TROPHAMINE 6% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-018 07-20-84		NS 09-24-86
AMINO ACIDS; CALCIUM ACETATE; GLYCERIN; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 3%; 26MG/100ML; 3GM/100ML; 54MG/100ML; 41MG/100ML; 149MG/100ML; 204MG/100ML; 117MG/100ML	PERIPHAMINE (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-582 05-08-82		NC 09-24-86
AMINO ACIDS; DEXTROSE 3.5%; 5%	AMINOSYN 3.5% W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-120 10-11-84		
AMINO ACIDS; DEXTROSE 3.5%; 25%	AMINOSYN 3.5% W/ DEXTROSE 25% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-118 10-11-84		
AMINO ACIDS; DEXTROSE 4.25%; 25%	AMINOSYN 4.25% W/ DEXTROSE 25% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-119 10-11-84		
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE 3.5%; 21MG/100ML; 40MG/100ML; 128MG/100ML; 234MG/100ML	AMINOSYN 3.5% M IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-804 05-15-84		NC 09-24-86

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	DOSEAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
AMINO ACIDS: MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE	3.5%; 21MG/100ML; 40MG/100ML; 128MG/100ML; 234MG/100ML	AMINOSYN 3.5% N	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-875	08-08-84			NC 09-24-86
AMINOACETIC ACID	1.5GM/100ML	AMINOACETIC ACID 1.5%	(IN PLASTIC CONTAINER SOLUTION; IRRIGATION)	TRAVENOL LABS	18-522	02-19-82			
AMINOCAPROIC ACID	250MG/ML	AMINOCAPROIC ACID	(INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-590	10-29-82			
AMINOGLUTETIMIMIDE	250MG	CYTADREN	(TABLET; ORAL)	CIBA/CIBA-GEIGY	18-202	10-29-80	3595960 3944671 07-27-88 03-16-93		
AMINOPHYLLINE	300MG/5ML	SOMOPHYLLIN	(ENEMA; RECTAL)	FISONS	18-232	04-02-82			NR 09-24-86
AMINOPHYLLINE: SODIUM CHLORIDE	100MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%	(IN PLASTIC CONTAINER INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924	12-12-84			
AMINOPHYLLINE: SODIUM CHLORIDE	200MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%	(IN PLASTIC CONTAINER INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924	12-12-84			
AMINOPHYLLINE: SODIUM CHLORIDE	400MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%	(IN PLASTIC CONTAINER INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924	12-12-84			
AMINOPHYLLINE: SODIUM CHLORIDE	500MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%	(IN PLASTIC CONTAINER INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924	12-12-84			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S) STRENGTH(S)</u>	<u>TRADE NAME (DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO. APPROVAL DATE</u>	<u>PATENT NO. EXP. DATE</u>	<u>EXCLUSIVITY EXP. DATE</u>
AMITRIPTYLINE HYDROCHLORIDE 10MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 04-07-61	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 25MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 07-05-74	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 50MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 04-07-61	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 75MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 10-28-76	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 100MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 10-28-76	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 150MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 09-17-76	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 10MG/ML	ELAVIL (INJECTABLE; INJECTION)	MS&D/MERCK	12-704 04-11-61	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE 12.5MG; 5MG	LIMBITROL (TABLET; ORAL)	HOFFMANN-LA ROCHE	16-949 12-23-77	4316897 02-23-99	
AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE 25MG; 10MG	LIMBITROL (TABLET; ORAL)	HOFFMANN-LA ROCHE	16-949 12-23-77	4316897 02-23-99	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 4MG	ETRAFON A (TABLET; ORAL)	SCHERING	14-713 12-30-65	3428735 02-18-86	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 2MG		ETRAFON 2-25	(TABLET; ORAL)	SCHERING	14-713	12-30-65	3428735	02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 2MG		ETRAFON-FORTE	(TABLET; ORAL)	SCHERING	14-713	12-30-65	3428735	02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 2MG		ETRAFON 2-10	(TABLET; ORAL)	SCHERING	14-713	12-30-65	3428735	02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 4MG		TRIAVIL 4-10	(TABLET; ORAL)	MS&D/MERCK	14-715	12-30-65	3428735	02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 2MG		TRIAVIL 2-25	(TABLET; ORAL)	MS&D/MERCK	14-715	08-23-65	3428735	02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 2MG		TRIAVIL 2-10	(TABLET; ORAL)	MS&D/MERCK	14-715	04-04-67	3428735	02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 4MG		TRIAVIL 4-25	(TABLET; ORAL)	MS&D/MERCK	14-715	08-25-65	3428735	02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 50MG; 4MG		TRIAVIL 4-50	(TABLET; ORAL)	MS&D/MERCK	14-715	03-15-78	3428735	02-18-86	
AMMONIUM LACTATE EQ 12% ACID		LAC-HYDRIN (LOTION; TOPICAL)		BRISTOL-MYERS	19-155	04-24-85			NCE 04-24-88
AMOXAPINE 25MG		ASENDIN (TABLET; ORAL)		LEDERLE LABS/AM CYAN	18-021	09-22-80	3546226	08-01-89	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
AMOXAPINE 50MG	ASENDIN (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-021 09-22-80	3546226 12-08-87 3663696 05-16-89 3681357 08-01-89	
AMOXAPINE 100MG	ASENDIN (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-021 09-22-80	3546226 12-08-87 3663696 05-16-89 3681357 08-01-89	
AMOXAPINE 150MG	ASENDIN (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-021 09-22-80	3546226 12-08-87 3663696 05-16-89 3681357 08-01-89	
AMRINONE LACTATE EQ 5MG BASE/ML	INOCOR (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	18-700 07-31-84	4072746 02-07-95	NCE 07-31-94
ASPIRIN; CAFFEINE; DIHYDROCODEINE BITARTRATE 356.4MG; 30MG; 16MG	SYNALGOS-DC (CAPSULE; ORAL)	IVES LABS/AMHO	11-483 09-06-83		
ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE 385MG; 30MG; 25MG	NORGESIC (TABLET; ORAL)	RIKER LABS/3M	13-416 10-27-82		
ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE 770MG; 60MG; 50MG	NORGESIC FORTE (TABLET; ORAL)	RIKER LABS/3M	13-416 10-27-82		
ASPIRIN; CAFFEINE; PROPXYPHENE HYDROCHLORIDE 389MG; 32.4MG; 32MG	DARVON COMPOUND (CAPSULE; ORAL)	ELI LILLY INDSTRS/PR	10-996 03-08-83		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
ASPIRIN: CAFFEINE; PROPIONPHENONE HYDROCHLORIDE	389MG; 32.4MG; 65MG			ELI LILLY INDSTRS/PR	10-996	03-08-83			
ASPIRIN: CARISOPRODOL	325MG; 200MG			WALLACE PHARMS/C-M	12-365	07-11-83			
ASPIRIN: CARISOPRODOL; CODEINE PHOSPHATE	325MG; 200MG; 16MG			WALLACE PHARMS/C-M	12-366	07-11-83			
ASPIRIN: NEPROBAMATE	325MG; 200MG			WYETH LABS/AMHO	11-702	12-29-83			
ASPIRIN: PENTAZOCINE HYDROCHLORIDE	325MG; EQ 12.5MG BASE			WINTHROP LABS/STERL	16-891	11-12-75			
ATENOLOL	50MG			STUART PHARMS/ICI AM	18-240	08-19-81			
ATENOLOL; CHLORTHALIDONE	100MG; 25MG			STUART PHARMS/ICI AM	18-760	06-08-84			
ATENOLOL	100MG			STUART PHARMS/ICI AM	18-240	08-19-81			
TENORMIN	(TABLET; ORAL)			STUART PHARMS/ICI AM	18-240	08-19-81			
TENORETIC 100	(TABLET; ORAL)			STUART PHARMS/ICI AM	18-760	06-08-84			
ASPIRIN: CARISOPRODOL	325MG; 200MG			WALLACE PHARMS/C-M	12-365	07-11-83			
ASPIRIN: CARISOPRODOL; CODEINE PHOSPHATE	325MG; 200MG; 16MG			WALLACE PHARMS/C-M	12-366	07-11-83			
ASPIRIN: NEPROBAMATE	325MG; 200MG			WYETH LABS/AMHO	11-702	12-29-83			
ASPIRIN: PENTAZOCINE HYDROCHLORIDE	325MG; EQ 12.5MG BASE			WINTHROP LABS/STERL	16-891	11-12-75			
ATENOLOL	50MG			STUART PHARMS/ICI AM	18-240	08-19-81			
ATENOLOL; CHLORTHALIDONE	100MG; 25MG			STUART PHARMS/ICI AM	18-760	06-08-84			

TABLE IV. NDA'S APPROVED FROM 7-7-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
ATENOLOL; CHLORTHALIDONE 50MG; 25MG	TENORETIC 50 (TABLET; ORAL)	STUART PHARMS/ICI AM	18-760 06-08-84	3663607 05-16-89 3934032 01-20-93 3836671 09-17-91	NC 09-24-86
ATRACURIUM BESYLATE 10MG/ML	TRACRIUM (INJECTABLE; INJECTION)	BURROUGHS WELLCOME	18-831 11-23-83	4179507 12-18-96	NCE 11-23-93
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE 0.025MG; 0.5MG	MOTOFEN HALF-STRENGTH (TABLET; ORAL)	MCNEIL LABORATORIES	17-744 07-14-78	3646207 02-28-89	
AURANOFIN 3MG	RIDAURA (CAPSULE; ORAL)	SK&F LABORATORIES	18-689 05-24-85	3635945 01-18-89 3708579 01-02-90	NCE 05-24-90
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE 0.025MG; 1MG	MOTOFEN (TABLET; ORAL)	MCNEIL LABORATORIES	17-744 07-14-78	3646207 02-28-89	
AZATADINE MALEATE 1MG	OPTIMINE (TABLET; ORAL)	SCHERING	17-601 03-29-77	3419565 12-31-85 3717647 02-20-90	
AZATADINE MALEATE; PSEUDOPHEDRINE SULFATE 1MG; 120MG	TRINALIN (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-506 03-23-82	3419565 12-31-85 3717647 02-20-90	NC 09-24-86
BACLOFEN 10MG	LIORESAL (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-851 11-22-77	3471548 10-07-86	
BACLOFEN 20MG	LIORESAL DS (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-851 01-20-82	3471548 10-07-86	NS 09-24-86
BECLOMETHANSONE DIPROPIONATE 0.042MG/INH	BECLOVENT (AEROSOL; INHALATION)	GLAXO	18-153 06-24-80	4414209 11-08-00	
BECLOMETHANSONE DIPROPIONATE 0.042MG/INH	VANCERIL (AEROSOL; INHALATION)	SCHERING	17-573 05-12-76	4414209 11-08-00	

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
BECLOMETHANSONE DIPROPIONATE	BECONASE	GLAXO	18-584	11-08-00	4414209	11-08-00	
0.042MG/INH	(AEROSOL; INHALATION/NASAL)		09-30-81	11-08-00			
BECLOMETHANSONE DIPROPIONATE	VANCENASE	SCHERING	18-521	11-08-00	4414209	11-08-00	
0.042MG/INH	(AEROSOL; INHALATION/NASAL)		09-24-81	11-08-00			
BENDROFLUMETHIAZIDE	NATURÉTIN-2.5	ER SQUIBB AND SONS	12-164	07-09-85	3392168	07-09-85	
2.5MG	(TABLET; ORAL)		12-07-59	07-09-85			
BENDROFLUMETHIAZIDE	NATURÉTIN-5	ER SQUIBB AND SONS	12-164	07-09-85	3392168	07-09-85	
5MG	(TABLET; ORAL)		12-07-59	07-09-85			
BENDROFLUMETHIAZIDE	NATURÉTIN-10	ER SQUIBB AND SONS	12-164	07-09-85	3392168	07-09-85	
10MG	(TABLET; ORAL)		03-29-77	07-09-85			
BENDROFLUMETHIAZIDE; MADOLOL	CORZIDE	ER SQUIBB AND SONS	18-647	09-21-93	3982021	09-21-93	NC
5MG; 40MG	(TABLET; ORAL)		05-25-83	09-21-93			
BENDROFLUMETHIAZIDE; MADOLOL	CORZIDE	ER SQUIBB AND SONS	18-647	09-21-93	3982021	09-21-93	NC
5MG; 80MG	(TABLET; ORAL)		05-25-83	09-21-93			
BENTIRUMIDE	CHYMEX	ADRIA LABORATORIES	18-366	12-29-83	3801562	12-29-83	NC
500MG/7.5ML	(SOLUTION; ORAL)		12-29-83	04-02-91			
BETAMETHASONE	CELESTONE	SCHERING	12-657	04-17-61	3485854	12-23-86	
0.6MG	(TABLET; ORAL)		04-17-61	12-23-86			
BETAMETHASONE	CELESTONE	SCHERING	14-215	04-18-64	3485854	12-23-86	
0.6MG/5ML	(SYRUP; ORAL)		04-18-64	12-23-86			
BETAMETHASONE	CELESTONE	SCHERING	14-762	04-10-64	3485854	12-23-86	
0.2%	(CREAM; TOPICAL)		04-10-64	12-23-86			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
BETAMETHASONE ACETATE; BETAMETHASONE SODIUM PHOSPHATE 3MG/ML; EQ 3MG BASE/ML	CELESTONE SOLUSPAN (INJECTABLE; INJECTION)	SCHERING	14-602 03-03-65	3485854 12-23-86	
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	DIPROLENE (OINTMENT; TOPICAL)	SCHERING	18-741 07-27-83		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (CREAM; TOPICAL)	PHARMADERM/BYK-GLDN	19-136 06-26-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (CREAM; TOPICAL)	E FOUGERA/BYK-GLDN	19-137 06-26-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	ALPHATREX (CREAM; TOPICAL)	SAVAGE LABS/BYK-GLDN	19-138 06-26-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (OINTMENT; TOPICAL)	PHARMADERM/BYK-GLDN	19-140 09-04-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (OINTMENT; TOPICAL)	E FOUGERA/BYK-GLDN	19-141 09-04-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	ALPHATREX (OINTMENT; TOPICAL)	SAVAGE LABS/BYK-GLDN	19-143 09-04-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	DIPROSONE (CREAM; TOPICAL)	SCHERING	17-536 01-29-75		D-1 09-24-86
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	DIPROSONE (OINTMENT; TOPICAL)	SCHERING	17-691 04-15-76		D-1 09-24-86
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	DIPROSONE (LOTION; TOPICAL)	SCHERING	17-781 02-01-77		D-1 09-24-86
BETAMETHASONE DIPROPIONATE EQ 0.1% BASE	DIPROSONE (AEROSOL; TOPICAL)	SCHERING	17-829 05-24-77		D-1 09-24-86

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
BETAMETHASONE VALERATE	EQ 0.05% BASE; 1%	LOTRISONE	(CREAM; TOPICAL)	SCHERING	18-827	07-10-84	3660577	05-02-89	NC
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETA-VAL	(CREAM; TOPICAL)	LEMMON	18-642	03-24-83			
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETADERM	(CREAM; TOPICAL)	TJ ROACO	18-839	06-30-83			
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETAMETHASONE VALERATE	(CREAM; TOPICAL)	PHARMADERM/BYK-GLDN	18-860	08-31-83			
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETAMETHASONE VALERATE	(CREAM; TOPICAL)	E FOUGERA/BYK-GLDN	18-861	08-31-83			
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETATREX	(CREAM; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-862	08-31-83			
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETATREX	(CREAM; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-863	08-31-83			
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETAMETHASONE VALERATE	(OINTMENT; TOPICAL)	PHARMADERM/BYK-GLDN	18-864	08-31-83			
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETAMETHASONE VALERATE	(OINTMENT; TOPICAL)	E FOUGERA/BYK-GLDN	18-865	08-31-83			
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETAMETHASONE VALERATE	(OINTMENT; TOPICAL)	E FOUGERA/BYK-GLDN	18-866	08-31-83			
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETATREX	(LOTION; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-867	08-31-83			
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETAMETHASONE VALERATE	(LOTION; TOPICAL)	PHARMADERM/BYK-GLDN	18-870	08-31-83			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
BETHANIDINE SULFATE 10MG	TENATHAN (TABLET; ORAL)	AH ROBINS	17-675 05-29-81	3495013 02-10-87	
BETHANIDINE SULFATE 25MG	TENATHAN (TABLET; ORAL)	AH ROBINS	17-675 05-29-81	3495013 02-10-87	
BITOLTEROL MESYLATE 0.8%	TORNALATE (AEROSOL; INHALATION)	WINTHROP-BREON/STERL	18-770 12-28-84	4138581 02-06-96	NCE 12-28-89
BRETYLIUM TOSYLATE 50MG/ML	BRETYLOL (INJECTABLE; INJECTION)	AM CRITICAL CARE/AHS	17-954 07-18-78	RE29618 04-29-86	
BROMOCRIPTINE MESYLATE EQ 2.5MG BASE	PARLODEL (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	17-962 06-28-78	3752888 08-14-90 3752814 08-14-90	I-16 12-14-87
BROMOCRIPTINE MESYLATE EQ 5MG BASE	PARLODEL (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	17-962 03-01-82	3752888 08-14-90 3752814 08-14-90	I-16 12-14-87
BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE 12.5MG/5ML; 10MG/5ML	AMBENYL (SYRUP; ORAL)	MARION LABORATORIES	09-319 01-10-84		
BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 12.5MG/5ML	DIMETANE-DC (SYRUP; ORAL)	AH ROBINS	11-694 03-29-84		
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AH ROBINS	11-694 03-29-84		
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AH ROBINS	19-279 08-24-84		

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 4MG/5ML; 25MG/5ML	ELIXIR DIMETAPP (ELIXIR; ORAL)		AH ROBINS	13-087				
BUMETANIDE 1MG	BUMEX (TABLET; ORAL)		HOFFMANN-LA ROCHE	18-225	02-28-83	01-11-89 3634583 3806534 04-23-91	02-28-93 NCE	
BUMETANIDE 0.5MG	BUMEX (TABLET; ORAL)		HOFFMANN-LA ROCHE	18-225	02-28-83	01-11-89 3634583 3806534 04-23-91	02-28-93 NCE	
BUMETANIDE 0.25MG/ML	BUMEX (INJECTABLE; INJECTION)		HOFFMANN-LA ROCHE	18-226	02-28-83	01-11-89 3634583 3806534 04-23-91	02-28-93 NCE	
BUPIVACAINE HYDROCHLORIDE; DEXTROSE 0.75%; 8.25%	MARCAINE SPINAL (INJECTABLE; INJECTION)		BREON LABS/STERLING	18-692	05-04-84		NC	09-24-86
BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE 0.5%; 0.0091MG/ML	SENSEORCAINE (INJECTABLE; INJECTION)		ASTRA PHARM PRODS	18-304	09-02-83			
BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE 0.75%; 0.0091MG/ML	SENSEORCAINE (INJECTABLE; INJECTION)		ASTRA PHARM PRODS	18-304	09-02-83			
BUTORPHANOL TARTRATE 1MG/ML	STADOL (INJECTABLE; INJECTION)		BRISTOL LABS/B-M	17-857	08-22-78			
BUTORPHANOL TARTRATE 2MG/ML	STADOL (INJECTABLE; INJECTION)		BRISTOL LABS/B-M	17-857	08-22-78			
CALCEEDIOL, ANHYDROUS 0.02MG	CALDEROL (CAPSULE; ORAL)		UPJOHN	18-312	08-05-80			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CALCEFEDIOL, ANHYDROUS 0.05MG	CALDEROL (CAPSULE; ORAL)	UPJOHN	18-312 08-05-80	3833622 09-03-91 3565924 03-23-86	
CALCITONIN 200 IU/VIAL	CALCIMAR (INJECTABLE; INJECTION)	ARMOUR PHARM	17-769 12-21-84		I-18 12-21-87
CALCITONIN 400 IU/VIAL	CALCIMAR (INJECTABLE; INJECTION)	ARMOUR PHARM	17-497 12-21-84		I-18 12-21-87
CALCITRIOL 0.25 UGM	ROCALTROL (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-044 08-17-78	3697559 10-10-89 4391802 07-05-00 4341774 07-27-99 4225596 09-30-97	
CALCITRIOL 0.5 UGM	ROCALTROL (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-044 08-17-78	3697559 10-10-89 4391802 07-05-00 4341774 07-27-99 4225596 09-30-97	
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE 34MG/100ML; 5GM/100ML; 30MG/100ML; 74MG/100ML; 640MG/100ML; 500MG/100ML; 74MG/100ML	ISOLYTE E W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-269 01-17-83		

ACTIVE INGREDIENT(S) TRADE NAME (DOSAGE FORM, ROUTE) APPLICANT NAME NDA NO. APPROVAL DATE PATENT NO. EXP. DATE EXCLUSIVITY

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLIX	W/ DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMEO	18-883	11-30-84			
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLIX	W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMEO	18-883	11-30-84			
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLIX	W/ DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMEO	18-883	11-30-84			
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; 9.4GM/100ML; 11GM/100ML	AM MCGAW/AM HOSP	DIALYTE CONCENTRATE W/ DEXTROSE 50% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807	08-26-83			
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; 9.4GM/100ML; 11GM/100ML	AM MCGAW/AM HOSP	DIALYTE CONCENTRATE W/ DEXTROSE 30% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807	08-26-83			
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; 9.4GM/100ML; 11GM/100ML	AM MCGAW/AM HOSP	DIALYTE CONCENTRATE W/ DEXTROSE 50% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807	08-26-83			
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; 9.4GM/100ML; 11GM/100ML	AM MCGAW/AM HOSP	DIALYTE CONCENTRATE W/ DEXTROSE 30% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807	08-26-83			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLX W/ DEXTROSE 1.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLX W/ DEXTROSE 2.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLX W/ DEXTROSE 4.25% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 26MG/100ML; 2.5GM/100ML; 15MG/100ML; 560MG/100ML; 390MG/100ML	DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HQSP	18-460 11-02-83		

ACTIVE INGREDIENT(S) TRADE NAME (DOSAGE FORM, ROUTE) APPLICANT NAME NDA NO. APPROVAL DATE EXP. DATE PATENT NO. EXCLUSIVITY EXP. DATE

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	DEXTRASE 5% AND RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-635	02-07-83				
30MG/100ML; 56MG/100ML; 30MG/100ML; 860MG/100ML								
CALCIUM CHLORIDE; SODIUM ACETATE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	TPN ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-895	07-20-84				
121MG/ML; 16.1MG/ML; 16.5MG/ML; 25.4MG/ML; 74.6MG/ML; SODIUM CHLORIDE								
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE								
30MG/100ML; 860MG/100ML								
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE; 35MG/100ML; 30MG/100ML; 74MG/100ML; 640MG/100ML; 500MG/100ML; 74MG/100ML								
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM CHLORIDE; 325.3MG/100ML; 119.3MG/100ML; 643MG/100ML								
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 600MG/100ML	ACETATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGRAW/HM HOSP	18-725	11-29-82				
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; 30MG/100ML; 30MG/100ML; 860MG/100ML	RINGER'S IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-495	02-19-82				
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	RINGER'S INJECTION IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-648	02-07-83				
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGRAW/HM HOSP	18-721	11-09-82				

TABLE IV. NDA'S APPROVED FROM 7-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 105MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 105MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 179MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 179MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 254MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 254MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY	EXP. DATE
CALCIUM CHLORIDE; DEXTROSE;	310MG/100ML	POTASSIUM CHLORIDE	20MEQ IN DEXTROSE 5%	TRAVENOL LABS	19-367	04-05-85				
SODIUM LACTATE	20MG/100ML; 5GM/100ML;	AND LACTATED RINGER'S	IN PLASTIC CONTAINER							
POTASSIUM CHLORIDE; SODIUM	328MG/100ML; 600MG/100ML;	LACTATED RINGER'S	(INJECTABLE; INJECTION)	TRAVENOL LABS	19-367	04-05-85				
CALCIUM CHLORIDE; DEXTROSE;	310MG/100ML	POTASSIUM CHLORIDE	40MEQ IN DEXTROSE 5%	TRAVENOL LABS	19-367	04-05-85				
SODIUM LACTATE	20MG/100ML; 5GM/100ML;	AND LACTATED RINGER'S	IN PLASTIC CONTAINER							
POTASSIUM CHLORIDE; SODIUM	328MG/100ML; 600MG/100ML;	LACTATED RINGER'S	(INJECTABLE; INJECTION)	TRAVENOL LABS	18-494	02-19-82				
CALCIUM CHLORIDE; POTASSIUM	600MG/100ML; 310MG/100ML	LACTATED RINGER'S	IN PLASTIC CONTAINER							
SODIUM CHLORIDE; SODIUM	20MG/100ML; 30MG/100ML;	LACTATED RINGER'S	(SOLUTION; IRRIGATION)	AM MCGAW/AM HOSP	18-681	12-27-82				
CALCIUM CHLORIDE; POTASSIUM	600MG/100ML; 310MG/100ML	LACTATED RINGER'S	IN PLASTIC CONTAINER	TRAVENOL LABS	18-921	04-03-84				
SODIUM CHLORIDE; SODIUM	20MG/100ML; 30MG/100ML;	LACTATED RINGER'S	(SOLUTION; IRRIGATION)							
CALCIUM CHLORIDE; POTASSIUM	600MG/100ML; 310MG/100ML	LACTATED RINGER'S	IN PLASTIC CONTAINER	WINTHROP LABS/STERL	16-847	11-17-73				
MEGLUMINE METRIZOATE; SODIUM	0.78MG/ML; 0.15MG/ML; 75.9MG/ML;	ISOPAQUE 440	(INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-506	04-30-74				
CALCIUM; MEGLIUMINE; METRIZOIC	0.35MG/ML; 140.1MG/ML; 461.8MG/ML	ISOPAQUE 280	(INJECTABLE; INJECTION)	WINTHROP LABS/STERL	18-343	01-17-85				
CAPTOPRIL	12.5MG	CAPOTEN	(TABLET; ORAL)	ER SQUIBB AND SONS	18-343	01-17-85				

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CAPTOPRIL 25MG	CAPOTEN (TABLET; ORAL)	ER SQUIBB AND SONS	18-343 04-06-81	4105776 08-08-95	I-20 09-24-86 D-7 10-12-87
CAPTOPRIL 50MG	CAPOTEN (TABLET; ORAL)	ER SQUIBB AND SONS	18-343 04-06-81	4105776 08-08-95	I-20 09-24-86 D-7 10-12-87
CAPTOPRIL 100MG	CAPOTEN (TABLET; ORAL)	ER SQUIBB AND SONS	18-343 04-06-81	4105776 08-08-95	I-20 09-24-86 D-7 10-12-87
CAPTOPRIL; HYDROCHLOROTHIAZIDE 25MG; 15MG	CAPOZIDE 25/15 (TABLET; ORAL)	ER SQUIBB AND SONS	18-709 10-12-84	4105776 08-08-95 4217347 08-12-97	NC 10-12-87
CAPTOPRIL; HYDROCHLOROTHIAZIDE 50MG; 15MG	CAPOZIDE 50/15 (TABLET; ORAL)	ER SQUIBB AND SONS	18-709 10-12-84	4105776 08-08-95 4217347 08-12-97	NC 10-12-87
CAPTOPRIL; HYDROCHLOROTHIAZIDE 50MG; 25MG	CAPOZIDE 50/25 (TABLET; ORAL)	ER SQUIBB AND SONS	18-709 10-12-84	4105776 08-08-95 4217347 08-12-97	NC 10-12-87
CARBAMAZEPINE 200MG	TEGRETOL (TABLET; ORAL)	GEIGY/CIBA-GEIGY	16-608 03-11-68	4409212 10-11-00	
CARBAMAZEPINE 100MG	TEGRETOL (TABLET, CHEWABLE; ORAL)	GEIGY/CIBA-GEIGY	18-281 12-14-81	4409212 10-11-00	
CARBIDOPA 25MG	LODOSYN (TABLET; ORAL)	MS&D/MERCK	17-830 04-25-77	3462536 08-19-86 3830827 08-20-91 3781415 12-25-90	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	DOSEAGE FORM: ROUTE	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY	EXP. DATE
CARBOPROST TROMETHAMINE	EQ 0.25MG BASE/ML	SINEMET	(INJECTABLE: INJECTION)	UPJOHN	17-989	01-09-79	3728382	1-32	03-21-88	12-28-92
CELLULOSE SODIUM PHOSPHATE	2.5GM/PACKET	CALCIBIND	(POWDER: ORAL)	MISSION PHARMACAL	18-757	12-28-82	3728382	NCE		
CERULETIDE DIETHYLAMINE	0.02MG/ML	TYMTRAN	(INJECTABLE: INJECTION)	ADRIA LABORATORIES	18-296	12-24-81	3472832			
CARBIDOPA: LEVODOPA	25MG; 100MG	SINEMET	(TABLET: ORAL)	MS&D/MERCK	17-555	05-02-75	3462536			
CARBIDOPA: LEVODOPA	25MG; 250MG	SINEMET	(TABLET: ORAL)	MS&D/MERCK	17-555	05-02-75	3462536			
CARBIDOPA: LEVODOPA	10MG; 100MG	SINEMET	(TABLET: ORAL)	MS&D/MERCK	17-555	05-02-75	3462536			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CHENODIOL 250MG	CHENIX (TABLET; ORAL)	ROWELL LABORATORIES	18-513 07-28-83		NCE 07-28-93
CHLORDIAZEPOXIDE 25MG	LIBRITABS (TABLET; ORAL)	ROCHE PRODUCTS	13-071 10-31-66	4316897 02-23-99	
CHLORDIAZEPOXIDE 5MG	LIBRITABS (TABLET; ORAL)	ROCHE PRODUCTS	13-071 10-31-66	4316897 02-23-99	
CHLORDIAZEPOXIDE 10MG	LIBRITABS (TABLET; ORAL)	ROCHE PRODUCTS	13-071 10-31-66	4316897 02-23-99	
CHLORDIAZEPOXIDE 30MG	LIBRELEASE (CAPSULE, CONTROLLED RELEASE; ORAL)	HOFFMANN-LA ROCHE	17-813 09-12-83	4316897 02-23-99	NDF 09-24-86
CHLORDIAZEPOXIDE HYDROCHLORIDE 5MG	LIBRIUM (CAPSULE; ORAL)	ROCHE PRODUCTS	12-249 02-24-60	4316897 02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE 10MG	LIBRIUM (CAPSULE; ORAL)	ROCHE PRODUCTS	12-249 02-24-60	4316897 02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE 25MG	LIBRIUM (CAPSULE; ORAL)	ROCHE PRODUCTS	12-249 02-24-60	4316897 02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE 100MG/AMP	LIBRIUM (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	12-301 07-21-61	4316897 02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE; CLIDINIUM BROMIDE 5MG; 2.5MG	LIBRAX (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	12-750 05-02-61	4316897 02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED 5MG; 0.2MG	MENRIUM 5-2 (TABLET; ORAL)	HOFFMANN-LA ROCHE	14-740 10-27-69	4316897 02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED 5MG; 0.4MG	MENRIUM 5-4 (TABLET; ORAL)	HOFFMANN-LA ROCHE	14-740 10-27-69	4316897 02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED 10MG; 0.4MG	MENRIUM 10-4 (TABLET; ORAL)	HOFFMANN-LA ROCHE	14-740 10-27-69	4316897 02-23-99	

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
CHLOROXINE 2%	CAPITROL	(SHAMPOO; TOPICAL)	WESTWOOD PHARMS	17-594	10-19-76	3886277	05-27-92	
CHLOROTHALIDONE; CLONIDINE HYDROCHLORIDE 15MG; 0.1MG	COMBIPRES	(TABLET; ORAL)	BOEHRINGER INGELHEIM	17-503	08-22-74	3454701	07-08-86	
CHLOROTHALIDONE; CLONIDINE HYDROCHLORIDE 15MG; 0.2MG	COMBIPRES	(TABLET; ORAL)	BOEHRINGER INGELHEIM	17-503	08-22-74	3454701	07-08-86	
CHLOROTHALIDONE; CLONIDINE HYDROCHLORIDE 15MG; 0.3MG	COMBIPRES	(TABLET; ORAL)	BOEHRINGER INGELHEIM	17-503	04-10-84	3454701	07-08-86	
CHOLESTYRAHINE EQ 4GM RESIN/PACKET	QUESTRAN	(POWDER; ORAL)	HEAD JOHNSON/B-M	16-019	12-06-66		09-24-86	1-23
CHOLESTYRAHINE EQ 4GM RESIN/PACKET	QUESTRAN	(POWDER; ORAL)	HEAD JOHNSON/B-M	16-640	08-03-73		09-24-86	1-23
CHYMOPAPAIN 12,500 UNITS/VIAL	DISCASE	(INJECTABLE; INJECTION)	TRAVENOL LABS	18-625	01-18-84		11-10-92	NCE
CHYMOPAPAIN 10,000 UNITS/VIAL	CHYMODIACTIN	(INJECTABLE; INJECTION)	SMITH LABORATORIES	18-663	11-10-82	4439423	03-26-01	11-10-92
CHYMOPAPAIN 4,000 UNITS/VIAL	CHYMODIACTIN	(INJECTABLE; INJECTION)	SMITH LABORATORIES	18-663	08-21-84	4439423	03-26-01	11-10-92
CICLOPIRUX OLAMINE 1%	LOPROX	(CREAM; TOPICAL)	HOECHST-ROUSSEL	18-748	12-30-82	3883545	05-13-92	12-30-92
CIMETIDINE 200MG	TAGAMET	(TABLET; ORAL)	SK&F LAB	17-920	08-16-77	3950333	04-13-93	
CIMETIDINE 300MG	TAGAMET	(TABLET; ORAL)	SK&F LAB	17-920	08-16-77	3950333	04-13-93	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CIMETIDINE 400MG	TAGAMET (TABLET; ORAL)	SK&F LAB	17-920 12-14-83	3950333 04-13-93 4024271 05-17-94	NS 09-24-86
CIMETIDINE HYDROCHLORIDE EQ 300MG BASE/5ML	TAGAMET (SOLUTION; ORAL)	SK&F LAB	17-924 08-16-77	3950333 04-13-93 4024271 05-17-94	
CIMETIDINE HYDROCHLORIDE EQ 150MG BASE/ML	TAGAMET (INJECTABLE; INJECTION)	SK&F LAB	17-939 08-16-77	3950333 04-13-93 4024271 05-17-94	
CINOXACIN 250MG	CINOBAC (CAPSULE; ORAL)	ELI LILLY	18-067 06-13-80	3669965 06-13-89	
CINOXACIN 500MG	CINOBAC (CAPSULE; ORAL)	ELI LILLY	18-067 06-13-80	3669965 06-13-89	
CISPLATIN 0.5MG/ML	PLATINOL-AQ	BRISTOL LABS/B-M	18-057 07-18-84	4177263 12-04-96 4310515 01-12-99	NDF 09-24-86
CITRIC ACID; MAGNESIUM OXIDE; SODIUM CARBONATE 3.24GM/100ML; 380MG/100ML; 430MG/100ML	IRRIGATING SOLUTION G IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-519 06-22-82		NC 09-24-86
CITRIC ACID; MAGNESIUM OXIDE; SODIUM CARBONATE 3.24GM/100ML; 380MG/100ML; 430MG/100ML	UROLOGIC G IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	ABBOTT LABORATORIES	18-904 05-27-83		NC 09-24-86
CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE EQ 1MG BASE; 75MG	TAVIST D (TABLET, CONTROLLED RELEASE; ORAL)	DORSEY LABS/SANDOZ	18-298 12-15-82	3933999 01-20-93	NDF 09-24-86
CLOMIPHENE CITRATE 50MG	CLOMIPHENE CITRATE (TABLET; ORAL)	PLANTEK/IKAPHARM	18-361 03-22-82		

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
CLONAZEPAM 0.5MG	CLONOPIN	(TABLET; ORAL)	HOFFMANN-LA ROCHE	17-533	02-23-99	4316897		
CLONAZEPAM 1MG	CLONOPIN	(TABLET; ORAL)	HOFFMANN-LA ROCHE	17-533	06-04-75	4316897		
CLONAZEPAM 2MG	CLONOPIN	(TABLET; ORAL)	HOFFMANN-LA ROCHE	17-533	06-04-75	4316897		
CLONIDINE 2.5MG	CATAPRES-TTS-1	(FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891	10-10-84	3454701	07-08-86	NR
CLONIDINE 5MG	CATAPRES-TTS-2	(FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891	10-10-84	3454701	07-08-86	NR
CLONIDINE 7.5MG	CATAPRES-TTS-3	(FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891	10-10-84	3454701	07-08-86	NR
CLONIDINE HYDROCHLORIDE 0.1MG	CATAPRES	(TABLET; ORAL)	BOEHRINGER INGELHEIM	17-407	09-03-74	3454701	07-08-86	
CLONIDINE HYDROCHLORIDE 0.2MG	CATAPRES	(TABLET; ORAL)	BOEHRINGER INGELHEIM	17-407	09-03-74	3454701	07-08-86	
CLONIDINE HYDROCHLORIDE 0.3MG	CATAPRES	(TABLET; ORAL)	BOEHRINGER INGELHEIM	17-407	09-20-79	3454701	07-08-86	
CLORAZEPATE DIPOTASSIUM 3.75MG	TRANXENE	(CAPSULE; ORAL)	ABBOTT LABORATORIES	17-105	06-23-72	RE28315	06-23-87	
CLORAZEPATE DIPOTASSIUM 7.5MG	TRANXENE	(CAPSULE; ORAL)	ABBOTT LABORATORIES	17-105	06-23-72	RE28315	06-23-87	
CLORAZEPATE DIPOTASSIUM 15MG	TRANXENE	(CAPSULE; ORAL)	ABBOTT LABORATORIES	17-105	06-23-72	RE28315	06-23-87	
CLORAZEPATE DIPOTASSIUM 22.5MG	TRANXENE SD	(TABLET; ORAL)	ABBOTT LABORATORIES	17-105	03-31-75	RE28315	06-23-87	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CLORAZEPATE DIPOTASSIUM 11.25MG	TRANXENE SD (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 08-04-76	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 3.75MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 7.5MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 15MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLOTRIMAZOLE 1%	LOTIMIN (SOLUTION; TOPICAL)	SCHERING	17-613 02-03-75	3660577 05-02-89 3705172 12-05-89 3839573 10-01-91	
CLOTRIMAZOLE 1%	LOTIMIN (CREAM; TOPICAL)	SCHERING	17-619 03-18-75	3660577 05-02-89 3705172 12-05-89 3839573 10-01-91	
CLOTRIMAZOLE 1%	GYNE-LOTIMIN (CREAM; VAGINAL)	SCHERING	18-052 11-08-78	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 100MG	GYNE-LOTIMIN (TABLET; VAGINAL)	SCHERING	17-717 03-24-76	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 5-31-85 AND NDAs WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	DOSEAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
CLOTIRIMAZOLE	1%	MYCELEX	(SOLUTION; TOPICAL)	MILES PHARMS/MILES	18-181	01-15-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	05-02-89	
CLOTIRIMAZOLE	100MG	MYCELEX-G	(TABLET; VAGINAL)	MILES PHARMS/MILES	18-182	02-27-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	05-02-89	
CLOTIRIMAZOLE	500MG	MYCELEX-G	(TABLET; VAGINAL)	MILES PHARMS/MILES	19-069	04-19-85	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	05-02-89	NS 04-19-88
CLOTIRIMAZOLE	1%	MYCELEX	(CREAM; TOPICAL)	MILES PHARMS/MILES	18-183	01-15-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	05-02-89	
CLOTIRIMAZOLE	1%	MYCELEX-G	(CREAM; VAGINAL)	MILES PHARMS/MILES	18-230	02-16-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	05-02-89	
CLOTIRIMAZOLE	10MG	MYCELEX	(TROCHE/LOZENGE; ORAL)	MILES PHARMS/MILES	18-713	06-17-83	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	05-02-89	NDF 09-24-86

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CLOTRIMAZOLE 1%	LOTTRIMIN (LOTION; TOPICAL)	SCHERING	18-813 02-17-84	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE 10MG/5ML; 5MG/5ML; 6.25MG/5ML	PHENERGAN VC W/ CODEINE (SYRUP; ORAL)	WYETH LABS/AMHO	08-306 04-02-84		
CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE 10MG/5ML; 6.25MG/5ML	PHENERGAN W/ CODEINE (SYRUP; ORAL)	WYETH LABS/AMHO	08-306 04-02-84		
CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 10MG/5ML; 30MG/5ML; 1.25MG/5ML	ACTIFED W/ CODEINE (SYRUP; ORAL)	BURROUGHS WELLCOME	12-575 04-04-84		
COLESTIPOL HYDROCHLORIDE 5GM/PACKET	COLESTID (GRANULE; ORAL)	UPJOHN	17-563 04-04-77	3692895 09-19-89	I-24 09-24-86
COLESTIPOL HYDROCHLORIDE 500GM/BOT	COLESTID (GRANULE; ORAL)	UPJOHN	17-563 04-04-77	3692895 09-19-89	I-24 09-24-86
COPPER 89MG	CU-7 (INTRAUTERINE DEVICE; INTRAUTERINE)	SEARLE PHARMS	17-408 02-25-74	3563235 02-16-88 4040417 08-09-94 3783861 01-08-91 3803308 12-01-87 RE28399 04-29-92	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
COPPER	120MG	TATUM-T (INTRAVETERINE DEVICE; INTRAUTERINE)		SEARLE PHARMS	18-205	08-16-79	3563235 4040417 08-09-94 3783861 01-08-91 3803308 12-01-87 R328399 04-29-92		
CROMOLYN SODIUM	20MG	INITAL (CAPSULE; INHALATION)		FISONS	16-990	06-20-73	3686412 3777033 08-22-89 3419578 12-31-85	1-22	09-24-86
CROMOLYN SODIUM	4%	NASALCROM (SOLUTION; NASAL)		FISONS	18-306	03-18-83	3686412 3777033 08-22-89 3419578 12-31-85		09-24-86
CROMOLYN SODIUM	4%	OPTICROM (SOLUTION; OPHTHALMIC)		FISONS	18-155	10-03-84	3686412 3777033 08-22-89 3419578 12-31-85 3975536 08-17-93 4053628 10-11-94		10-03-87

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CROMOLYN SODIUM 10MG/ML	INTAL (SOLUTION; INHALATION)	FISONS	18-596 05-28-82	3686412 08-22-89 3777033 08-22-89 3419578 12-31-85 3975536 08-17-93	I-22 01-19-88
CYCLOBENZAPRINE HYDROCHLORIDE 5MG	FLEXERIL (TABLET; ORAL)	MS&D/MERCK	17-821 08-26-77	3454643 07-08-86 3882246 05-06-92	
CYCLOBENZAPRINE HYDROCHLORIDE 10MG	FLEXERIL (TABLET; ORAL)	MS&D/MERCK	17-821 08-26-77	3454643 07-08-86 3882246 05-06-92	
CYCLOPHOSPHAMIDE 1GM/VIAL	CYTOXAN (INJECTABLE; INJECTION)	MEAD JOHNSON/B-M	12-142 08-30-82		NS 09-24-86
CYCLOPHOSPHAMIDE 1GM/VIAL	NEOSAR (INJECTABLE; INJECTION)	ADRIA LABORATORIES	87-442 07-08-83		NS 09-24-86
CYCLOPHOSPHAMIDE 2GM/VIAL	CYTOXAN (INJECTABLE; INJECTION)	MEAD JOHNSON/B-M	12-142 08-30-82		NS 09-24-86
CYTARABINE 100MG/VIAL	CYTOSAR-U (INJECTABLE; INJECTION)	UPJOHN	16-793 06-17-69	3444294 05-13-86	
CYTARABINE 500MG/VIAL	CYTOSAR-U (INJECTABLE; INJECTION)	UPJOHN	16-793 06-17-69	3444294 05-13-86	
DANTROLENE SODIUM 25MG	DANTRIUM (CAPSULE; ORAL)	NORWICH EATON/P&G	17-443 01-15-74	3415821 12-10-85	
DANTROLENE SODIUM 100MG	DANTRIUM (CAPSULE; ORAL)	NORWICH EATON/P&G	17-443 01-15-74	3415821 12-10-85	
DANTROLENE SODIUM 50MG	DANTRIUM (CAPSULE; ORAL)	NORWICH EATON/P&G	17-443 10-10-75	3415821 12-10-85	
DANTROLENE SODIUM 20MG/VIAL	DANTRIUM (INJECTABLE; INJECTION)	NORWICH EATON/P&G	18-264 09-18-79	3415821 12-10-85	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DEPEROXAMINE MESYLATE	500MG/VIAL	DESERAL MESYLATE	(INJECTABLE; INJECTION)	CIBA/CIBA-GEIGY	16-267	04-01-68	3471476	10-07-86	
DESPRAMINE HYDROCHLORIDE	25MG	PERTOFRANE	(CAPSULE; ORAL)	USV LABORATORIES	13-621	12-18-64	3454698	07-08-86	
DESPRAMINE HYDROCHLORIDE	50MG	PERTOFRANE	(CAPSULE; ORAL)	USV LABORATORIES	13-621	04-10-68	3454698	07-08-86	
DESPRAMINE HYDROCHLORIDE	25MG	NORPRAMIN	(TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399	11-20-64	3454698	07-08-86	
DESPRAMINE HYDROCHLORIDE	50MG	NORPRAMIN	(TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399	01-09-67	3454698	07-08-86	
DESPRAMINE HYDROCHLORIDE	75MG	NORPRAMIN	(TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399	03-01-77	3454698	07-08-86	
DESPRAMINE HYDROCHLORIDE	100MG	NORPRAMIN	(TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399	03-01-77	3454698	07-08-86	
DESPRAMINE HYDROCHLORIDE	150MG	NORPRAMIN	(TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399	03-01-77	3454698	07-08-86	
DESPRAMINE HYDROCHLORIDE	10MG	NORPRAMIN	(TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399	02-11-82	3454698	07-08-86	NS

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S) STRENGTH(S)</u>	<u>TRADE NAME (DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO. APPROVAL DATE</u>	<u>PATENT NO. EXP. DATE</u>	<u>EXCLUSIVITY EXP. DATE</u>
DESMOPRESSIN ACETATE 0.01%	DDAVP (SOLUTION; NASAL)	ARMOUR PHARM	17-922 02-21-78	3497491 02-24-87	
DESMOPRESSIN ACETATE 0.004MG/ML	DDAVP (INJECTABLE; INJECTION)	ARMOUR PHARM	18-938 03-30-84	3497491 02-24-87	NDF 09-24-86
DESONIDE 0.05%	DESOWEN (CREAM; TOPICAL)	OWEN LABS/DERM PRODS	19-048 12-14-84		
DESOXIMETASONE 0.05%	TOPICORT (GEL; TOPICAL)	HOECHST-ROUSSEL	18-586 03-29-82		NDF 09-24-86
DESOXIMETASONE 0.05%	TOPICORT (OINTMENT; TOPICAL)	HOECHST-ROUSSEL	18-594 01-17-85		NDF 09-24-86
DESOXIMETASONE 0.25%	TOPICORT (OINTMENT; TOPICAL)	HOECHST-ROUSSEL	18-763 09-30-83		NDF 09-24-86
DEXAMETHASONE 6MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 07-30-82		NS 09-24-86
DEXAMETHASONE 6MG	DEXAMETHASONE (TABLET; ORAL)	PAR PHARMACEUTICAL	88-481 11-28-83		NS 09-24-86
DEXAMETHASONE 6MG	DEXAMETHASONE (TABLET; ORAL)	ROXANE LABORATORIES	88-316 09-15-83		NS 09-24-86
DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE 15MG/5ML; 6.25MG/5ML	PHENERGAN W/ DEXTROMETHORPHAN (SYRUP; ORAL)	WYETH LABS/AMHO	11-265 04-02-84		
DEXTROSE 60GM/100ML	DEXTROSE 60% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	17-521 03-26-82		
DEXTROSE 70GM/100ML	DEXTROSE 70% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	17-521 03-26-82		

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DEXTROSE 60GM/100ML	DEXTROSE 60% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-346	01-25-85			
DEXTROSE 30GM/100ML	DEXTROSE 30% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-345	01-26-85			
DEXTROSE 60GM/100ML	DEXTROSE 60% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	17-995	04-27-78	3729568	04-24-90	
DEXTROSE 60GM/100ML	DEXTROSE 60% INJECTABLE; INJECTION)	(INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	17-995	09-22-82	3729568	04-24-90	
DEXTROSE 70GM/100ML	DEXTROSE 70% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-561	03-23-82			
DEXTROSE 40GM/100ML	DEXTROSE 40% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-562	03-23-82			
DEXTROSE 50GM/100ML	DEXTROSE 50% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-563	03-23-82			
DEXTROSE 20GM/100ML	DEXTROSE 20% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-564	03-23-82			
DEXTROSE 38.5GM/100ML	DEXTROSE 38.5% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-923	09-19-84			
DEXTROSE 50MG/ML	DEXTROSE 5% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-222	07-13-84			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 80MG/100ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 02-04-82		NC 09-24-86
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 160MG/100ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 02-04-82		NC 09-24-86
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 80MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		NC 09-24-86
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 160MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		NC 09-24-86
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 320MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		NC 09-24-86
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 200 UNITS/100ML	HEPARIN SODIUM 1,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-130 12-31-83		NC 09-24-86
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 200 UNITS/100ML	HEPARIN SODIUM 2,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-130 12-31-83		NC 09-24-86
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 1,000 UNITS/100ML	HEPARIN SODIUM 5,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-130 12-31-83		NC 09-24-86
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 4,000 UNITS/100ML	HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-814 10-31-83		NC 09-24-86

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DEXTRROSE; HEPARIN SODIUM 5GM/100ML; 10,000 UNITS/100ML		HEPARIN SODIUM 12,500 UNITS IN DEXTROSE 5% (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	18-911	01-30-85			
DEXTRROSE; HEPARIN SODIUM 5GM/100ML; 5,000 UNITS/100ML		HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	19-339	03-27-85			
DEXTRROSE; HEPARIN SODIUM 5GM/100ML; 5,000 UNITS/100ML		HEPARIN SODIUM 25000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		AM MCGAW/AM HOSP	19-134	03-29-85			
DEXTRROSE; HEPARIN SODIUM 5GM/100ML; 10,000 UNITS/100ML		HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	18-911	01-30-85			
DEXTRROSE; HEPARIN SODIUM 5GM/100ML; 10,000 UNITS/100ML		HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	19-339	03-27-85			
DEXTRROSE; HEPARIN SODIUM 5GM/100ML; 10,000 UNITS/100ML		HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	18-911	01-30-85			

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 5-31-85 AND NDAs WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 10,000 UNITS/100ML	HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-339 03-27-85		
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-388 11-05-82		NS 09-24-86
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-461 02-22-82		NS 09-24-86
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 200MG/100ML	LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84		NS 09-24-86
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 400MG/100ML	LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84		NS 09-24-86
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84		NS 09-24-86
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE DIBASIC; SODIUM ACETATE 5GM/100ML; 31MG/100ML; 130MG/100ML; 26MG/100ML; 320MG/100ML	ISOLYTE P W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-025 12-27-84		

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 5-31-85 AND NDAs WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DEXTRIOSE: OXYTOCIN	SGM/100ML; 1 USP UNIT/100ML	OXYTOCIN	1 USP UNIT/100ML	ABBOTT LABORATORIES	19-185	03-29-85			
DEXTRIOSE: OXYTOCIN	SGM/100ML; 1 USP UNIT/100ML	OXYTOCIN	1 USP UNIT/100ML	ABBOTT LABORATORIES	19-185	03-29-85			
DEXTRIOSE: OXYTOCIN	SGM/100ML; 2 USP UNIT/100ML	OXYTOCIN	2 USP UNIT/100ML	ABBOTT LABORATORIES	19-185	03-29-85			
DEXTRIOSE: OXYTOCIN	SGM/100ML; 2 USP UNIT/100ML	OXYTOCIN	2 USP UNIT/100ML	ABBOTT LABORATORIES	19-185	03-29-85			
DEXTRIOSE: POTASSIUM CHLORIDE	SGM/100ML; 75MG/100ML	POTASSIUM CHLORIDE	75MG/100ML	AM MCGAW/AM HOSP	18-744	11-09-82			
DEXTRIOSE: POTASSIUM CHLORIDE	SGM/100ML; 150MG/100ML	POTASSIUM CHLORIDE	150MG/100ML	AM MCGAW/AM HOSP	18-744	11-09-82			
DEXTRIOSE: POTASSIUM CHLORIDE	SGM/100ML; 220MG/100ML	POTASSIUM CHLORIDE	220MG/100ML	AM MCGAW/AM HOSP	18-744	11-09-82			
DEXTRIOSE: POTASSIUM CHLORIDE	SGM/100ML; 300MG/100ML	POTASSIUM CHLORIDE	300MG/100ML	AM MCGAW/AM HOSP	18-744	11-09-82			
DEXTRIOSE: POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	120MG/100ML; 220MG/100ML; 100MG/100ML	POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	100MG/100ML; 220MG/100ML; 120MG/100ML	TRAVENOL LABS	18-840	06-29-83			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	DOSEAGE FORM, ROUTE	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	5GM/100ML; 224MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		TRAVENOL LABS	18-567	02-16-83			
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	5GM/100ML; 150MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		TRAVENOL LABS	18-567	02-16-83			
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	5GM/100ML; 300MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		TRAVENOL LABS	18-566	02-10-83			
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	5GM/100ML; 224MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		TRAVENOL LABS	18-566	02-10-83			
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	5GM/100ML; 150MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		TRAVENOL LABS	18-566	02-10-83			
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	5GM/100ML; 300MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		TRAVENOL LABS	18-566	02-10-83			
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	5GM/100ML; 224MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		TRAVENOL LABS	18-566	02-10-83			
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	5GM/100ML; 150MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		TRAVENOL LABS	18-566	02-10-83			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROVED PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 5MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DEXTROROSE; THEOPHYLLINE CHLORIDE	5GM/100ML; 224MG/100ML; 330MG/100ML	DEXTROROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	0.33% AND POTASSIUM CHLORIDE 30MG IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629	03-23-82			
DEXTROROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	5GM/100ML; 300MG/100ML; 330MG/100ML	DEXTROROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 40MG IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		TRAVENOL LABS	18-629	03-23-82			
DEXTROROSE; THEOPHYLLINE	5GM/100ML; 40MG/100ML	THEOPHYLLINE IN DEXTROROSE 5% (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	19-211	12-14-84			
DEXTROROSE; THEOPHYLLINE	5GM/100ML; 40MG/100ML	THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		AM HCGAM/AM HOSP	19-083	11-07-84			
DEXTROROSE; THEOPHYLLINE	5GM/100ML; 80MG/100ML	THEOPHYLLINE IN DEXTROROSE 5% (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	19-211	12-14-84			
DEXTROROSE; THEOPHYLLINE	5GM/100ML; 80MG/100ML	THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		AM HCGAM/AM HOSP	19-083	11-07-84			
DEXTROROSE; THEOPHYLLINE	5GM/100ML; 160MG/100ML	THEOPHYLLINE IN DEXTROROSE 5% (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	19-211	12-14-84			
DEXTROROSE; THEOPHYLLINE	5GM/100ML; 160MG/100ML	THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		AM HCGAM/AM HOSP	19-083	11-07-84			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
DEXTROSE; THEOPHYLLINE 5GM/100ML; 200MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 200MG/100ML	THEOPHYLLINE 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-212 11-07-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 400MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 400MG/100ML	THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-212 11-07-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 400MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 80MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 160MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 200MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 400MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		

STRENGTH(S)	ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY	EXP. DATE
DIATRIZATE	MEGLUMINE	RENO-M-DIP	(INJECTABLE; INJECTION)	ER SQUIBB AND SONS	10-04-01	01-08-60	09-24-86	I-7: I-8	09-24-86
DIATRIZATE	MEGLUMINE: 30%	RENOMAFIN-60	(INJECTABLE; INJECTION)	ER SQUIBB AND SONS	10-04-00	08-29-74	09-24-86	I-8	09-24-86
DIATRIZATE	MEGLUMINE: 52%; 8%	RENOMAFIN-76	(INJECTABLE; INJECTION)	ER SQUIBB AND SONS	10-04-00	10-27-72	09-24-86	I-5	09-24-86
DIATRIZATE	MEGLUMINE: 66%; 10%	VALIUM	(TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263	11-15-63	4316897		
DIATRIZATE	MEGLUMINE: 2MG	VALIUM	(TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263	11-15-63	4316897		
DIATRIZATE	MEGLUMINE: 5MG	VALIUM	(TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263	11-15-63	4316897		
DIATRIZATE	MEGLUMINE: 10MG	VALIUM	(TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263	11-15-63	4316897		
DIATRIZATE	MEGLUMINE: 5MG/ML	VALIUM	(INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	10-087	08-24-66	4316897		
DIATRIZATE	MEGLUMINE: 15MG	VALIUM	(CAPSULE; CONTROLLED RELEASE; ORAL)	HOFFMANN-LA ROCHE	18-179	03-12-81	4316897		
DIATRIZATE	MEGLUMINE: 15MG/ML	HYPERSTAT	(INJECTABLE; INJECTION)	SCHERING	16-996	01-22-73			
DIATRIZATE	MEGLUMINE: 15MG/ML	BENTYL	(CAPSULE; ORAL)	MERRILL DOW/DOW CHEM	07-409	10-15-84			
DIATRIZATE	MEGLUMINE: 20MG	BENTYL	(CAPSULE; ORAL)	MERRILL DOW/DOW CHEM	07-409	10-15-84			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
DICYCLOMINE HYDROCHLORIDE 10MG/ML	BENTYL (INJECTABLE; INJECTION)	MERRELL DOW/DOW CHEM	08-370 10-15-84		
DICYCLOMINE HYDROCHLORIDE 10MG/5ML	BENTYL (SYRUP; ORAL)	MERRELL DOW/DOW CHEM	07-961 10-15-84		
DIFLORASONE DIACETATE 0.05%	FLORONE (CREAM; TOPICAL)	UPJOHN	17-741 09-14-77	3980778 09-14-93	
DIFLORASONE DIACETATE 0.05%	FLORONE (OINTMENT; TOPICAL)	UPJOHN	17-994 03-01-78	3980778 09-14-93	
DIFLUNISAL 250MG	DOLOBID (TABLET; ORAL)	MS&D/MERCK	18-445 04-19-82	3714226 08-01-89 3674870 07-04-89	NCE 04-19-92
DIFLUNISAL 500MG	DOLOBID (TABLET; ORAL)	MS&D/MERCK	18-445 04-19-82	3714226 08-01-89 3674870 07-04-89	NCE 04-19-92
DIGOXIN 0.2MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82		NDF 09-24-86
DIGOXIN 0.05MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82		NDF 09-24-86
DIGOXIN 0.15MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 09-24-84		NS 09-24-86
DIGOXIN 0.1MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82		NDF 09-24-86
DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE 0.5MG/0.5ML; 2500 UNITS/0.5ML; 5.33MG/0.5ML	EMBOLEX (INJECTABLE; INJECTION)	SANDOZ PHARMS/SANDOZ	18-885 11-30-84	4451458 05-29-01 4402949 09-06-00	NC 11-30-87

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE 7.46MG/0.7ML; 0.5MG/0.7ML; 5000 UNITS/0.7ML;		EMBOLEX	(INJECTABLE; INJECTION)	SANDOZ PHARMS/SANDOZ	18-885	11-30-84	4451458 4402949 09-06-00	11-30-87	NC
DILTIAZEM HYDROCHLORIDE	30MG	CARDIZEM	(TABLET; ORAL)	MARION LABORATORIES	18-602	11-05-82	3562257	11-05-92	NCE
DILTIAZEM HYDROCHLORIDE	60MG	CARDIZEM	(TABLET; ORAL)	MARION LABORATORIES	18-602	11-05-82	3562257	11-05-92	NCE
DIMETHYL SULFOXIDE	50%	RIMS-50	(SOLUTION; URETHRAL)	RESEARCH INDUSTRIES	17-788	04-04-78	3549770	11-05-92	
DINOPROST IRONETAMINE	EQ 5MG BASE/ML	PROSTIN F2 ALPHA	(INJECTABLE; INJECTION)	UPJOHN	17-434	11-26-73	3657327 3706789 12-19-89 3778506 12-11-90		
DINOPROSTONE	20MG	PROSTIN EZ	(SUPPOSITORY; VAGINAL)	UPJOHN	17-810	08-23-77	3899587 3598858 08-12-92		
DIPIVEFRIN HYDROCHLORIDE	0.1%	PROPINE	(SOLUTION; OPHTHALMIC)	ALLERGAN PHARMS	18-239	05-02-80	3839584 10-01-91 3809714 05-07-91		
DISOPYRAMIDE PHOSPHATE	EQ 100MG BASE	NORPAC CR	(CAPSULE; CONTROLLED RELEASE; ORAL)	SEARLE/SEARLE PHARMS	18-655	07-20-82		09-24-86	NDF
DISOPYRAMIDE PHOSPHATE	EQ 150MG BASE	NORPAC CR	(CAPSULE; CONTROLLED RELEASE; ORAL)	SEARLE/SEARLE PHARMS	18-655	07-20-82		09-24-86	NDF
DIVALPROEX SODIUM	EQ 250MG BASE	DEPAKOTE	(TABLET, ENTERIC COATED; ORAL)	ABBOTT LABORATORIES	18-723	03-10-83		09-24-86	NE

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DIVALPROEX SODIUM EQ 500MG BASE	DEPAKOTE (TABLET, ENTERIC COATED; ORAL)	ABBOTT LABORATORIES	18-723 03-10-83		NE 09-24-86
DOBUTAMINE HYDROCHLORIDE EQ 250MG BASE/VIAL	DOBUTREX (INJECTABLE; INJECTION)	ELI LILLY	17-820 07-18-78	3987200 10-19-93	
DOPAMINE HYDROCHLORIDE 80MG/ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 07-09-82		
DOPAMINE HYDROCHLORIDE 80MG/ML	DOPAMINE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-398 03-22-82		
DOPAMINE HYDROCHLORIDE 40MG/ML	DOPAMINE HCL (INJECTABLE; INJECTION)	BRISTOL LABS/B-M	18-549 03-11-83		
DOPAMINE HYDROCHLORIDE 40MG/ML	DOPAMINE (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-656 06-28-83		
DOXEPIN HYDROCHLORIDE EQ 25MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 09-23-69	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 50MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 09-23-69	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 10MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 03-31-75	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 100MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 03-31-75	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 75MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 06-04-76	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 150MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 03-15-78	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 10MG BASE	ADAPIN (CAPSULE; ORAL)	PENNHALT PHARM	16-987 01-31-72	3420851 01-07-86	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DOXEPIN HYDROCHLORIDE	EQ 25MG BASE	ADAPIN	(CAPSULE; ORAL)	PENNMALT PHARM	16-987	01-31-72	3420851	01-07-86	
DOXEPIN HYDROCHLORIDE	EQ 50MG BASE	ADAPIN	(CAPSULE; ORAL)	PENNMALT PHARM	16-987	01-31-72	3420851	01-07-86	
DOXEPIN HYDROCHLORIDE	EQ 100MG BASE	ADAPIN	(CAPSULE; ORAL)	PENNMALT PHARM	16-987	12-12-77	3420851	01-07-86	
DOXEPIN HYDROCHLORIDE	EQ 75MG BASE	ADAPIN	(CAPSULE; ORAL)	PENNMALT PHARM	16-987	04-15-80	3420851	01-07-86	
DOXEPIN HYDROCHLORIDE	EQ 10MG BASE/ML	SINEQUAN	(CONCENTRATE; ORAL)	PFIZER LABS/PFIZER	17-516	03-11-74	3420851	01-07-86	
DRONABINOL	2.5MG	MARINOL	(CAPSULE; ORAL)	UNIMED	18-651	05-31-85			NCE
DRONABINOL	5MG	MARINOL	(CAPSULE; ORAL)	UNIMED	18-651	05-31-85			NCE
DRONABINOL	10MG	MARINOL	(CAPSULE; ORAL)	UNIMED	18-651	05-31-85			NCE
DRONABINOL	2.5MG	MARINOL	(CAPSULE; ORAL)	UNIMED	18-651	05-31-85			NCE
DRONABINOL	10MG	MARINOL	(CAPSULE; ORAL)	UNIMED	18-651	05-31-85			NCE
DRONABINOL	2.5MG	MARINOL	(CAPSULE; ORAL)	UNIMED	18-651	05-31-85			NCE
DRONABINOL	10MG	MARINOL	(CAPSULE; ORAL)	UNIMED	18-651	05-31-85			NCE
ECONAZOLE NITRATE	1%	SPECTAZOLE	(CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	18-751	12-23-82	3717555	02-20-90	NCE
ENFLURANE	99.9%	ETHRANE	(LIQUID; INHALATION)	ANQUEST/BOC	17-087	08-28-72	3469011	10-01-91	
EPINEPHRINE; ETIDOCALINE HYDROCHLORIDE	0.005MG/ML; 0.5%	DURANEST	(INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751	08-30-76	3862321	01-21-92	
							3812147	05-21-91	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROVED PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE 0.005MG/ML; 1%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE 0.005MG/ML; 1.5%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
ERGOLOID MESYLATES 1MG	HYDERGINE LC (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-706 01-18-83	4366145 12-28-99	NDF 09-24-86
ERGOLOID MESYLATES 1MG	HYDERGINE (SOLUTION; ORAL)	SANDOZ PHARMS/SANDOZ	18-418 01-30-81	4138565 02-06-96	
ESTRADIOL 0.01%	ESTRACE (CREAM; VAGINAL)	MEAD JOHNSON/B-M	86-069 01-31-84	4436738 03-13-01	NDF 09-24-86
ESTROGENS, CONJUGATED 0.9MG	PREMARIN (TABLET; ORAL)	AYERST LABS/AMHO	04-782 01-26-84		NS 09-24-86
ETHINYL ESTRADIOL; LEVONORGESTREL 0.03MG; 0.15MG	NORDETTE-21 (TABLET; ORAL-21)	WYETH LABS/AMHO	18-668 05-10-82	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	NC 09-24-86
ETHINYL ESTRADIOL; LEVONORGESTREL 0.03MG; 0.15MG	NORDETTE-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	18-782 07-21-82	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	NC 09-24-86
ETHINYL ESTRADIOL; LEVONORGESTREL .03MG; 0.05MG 0.04MG; 0.075MG 0.03MG; 0.125MG	TRIPHASIL-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	19-190 11-01-84	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91 3957982 05-18-93	NS 11-01-87

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
ETHINYL ESTRADIOL; LEVONORGESTREL	0.03MG; 0.05MG 0.04MG; 0.075MG 0.03MG; 0.125MG	TRIPHASIL-21	(TABLET; ORAL-21)	WYETH LABS/AMHO	19-192	11-01-84	3666858	05-30-89 11-26-91 3959322 11-26-91 3957982 05-18-93	NS 11-01-87
ETHINYL ESTRADIOL; NORETHINDRONE	0.035MG; 0.5MG AND 1MG	ORTHONOVUM 10/11-21	(TABLET; ORAL-21)	ORTHOPHARMACEUTICAL	18-354	01-11-82			D-5 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE	0.035MG; 0.5MG AND 1MG	ORTHONOVUM 10/11-28	(TABLET; ORAL-28)	ORTHOPHARMACEUTICAL	18-354	01-11-82			D-5 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE	0.035MG; 0.5MG AND 1MG	TRI-NORINYL 21-DAY	(TABLET; ORAL-21)	SYNTEX (FP)	18-977	04-13-84	4390531		D-6 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE	0.035MG; 0.5MG AND 1MG	TRI-NORINYL 28-DAY	(TABLET; ORAL-28)	SYNTEX (FP)	18-977	04-13-84	4390531		D-6 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE	0.035MG; 0.5MG, 0.75MG AND 1MG	ORTHONOVUM 7/77-21	(TABLET; ORAL-21)	ORTHOPHARMACEUTICAL	18-985	04-04-84			D-3 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE	0.035MG; 0.5MG, 0.75MG AND 1MG	ORTHONOVUM 7/77-28	(TABLET; ORAL-28)	ORTHOPHARMACEUTICAL	18-985	04-04-84			D-3 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE	0.035MG; 0.5MG AND 1MG	ORTHONOVUM 7/14-21	(TABLET; ORAL-21)	ORTHOPHARMACEUTICAL	19-004	04-04-84			D-4 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE	0.035MG; 0.5MG AND 1MG	ORTHONOVUM 7/14-28	(TABLET; ORAL-28)	ORTHOPHARMACEUTICAL	19-004	04-04-84			D-4 09-24-86
ETHINYL ESTRADIOL; NORGESTREL	0.05MG; 0.5MG	OVRAL	(TABLET; ORAL-21)	WYETH LABS/AMHO	16-672	04-16-68	3666858		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
ETHINYL ESTRADIOL; NORGESTREL 0.05MG; 0.5MG	OVRAL-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	16-806 11-26-68	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETHINYL ESTRADIOL; NORGESTREL 0.03MG; 0.3MG	LO/OVRAL (TABLET; ORAL-21)	WYETH LABS/AMHO	17-612 03-17-75	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETHINYL ESTRADIOL; NORGESTREL 0.03MG; 0.3MG	LO/OVRAL-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	17-802 03-16-76	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETIDOCAINE HYDROCHLORIDE 0.5%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
ETIDOCAINE HYDROCHLORIDE 1%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
ETIDRONATE DISODIUM 200MG	DIDRONEL (TABLET; ORAL)	NORWICH EATON/P&G	17-831 09-01-77	4254114 03-03-98 4216211 08-05-97 4137309 01-30-96 3683080 08-08-89	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	DOSEAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
ETIDRONATE DISODIUM	400MG	DIDRONEL	(TABLET; ORAL)	NORMICH EATON/P&G	17-831	07-06-84	4254114	03-03-98	NS
ETOMIDATE	2MG/ML	AMIDATE	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-227	09-07-82	08-08-89 3683080 01-30-96 4137309 08-05-97 4216211	09-07-92	NCE
ETOPOSIDE	20MG/ML	VEPESID	(INJECTABLE; INJECTION)	BRISTOL LABS/B-M	18-768	11-10-83	3524844	08-18-87	NCE
FENFLURAMINE HYDROCHLORIDE	60MG	PONDMIN	(TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINSON	16-618	07-27-82		09-24-86	NDF
FENOPROFEN CALCIUM	EQ 300MG BASE	MALFON	(CAPSULE; ORAL)	DISTA PRODS/LILLY	17-604	03-16-76	3600437	08-17-88	
FENOPROFEN CALCIUM	EQ 200MG BASE	MALFON 200	(CAPSULE; ORAL)	DISTA PRODS/LILLY	17-604	10-15-80	3600437	08-17-88	
FENOPROFEN CALCIUM	EQ 600MG BASE	MALFON	(TABLET; ORAL)	DISTA PRODS/LILLY	17-710	03-16-76	3600437	08-17-88	
FENTANYL CITRATE	EQ 0.05MG BASE/ML	FENTANYL CITRATE	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-115	01-12-85			
FENTANYL CITRATE	EQ 0.05MG BASE/ML	FENTANYL	(INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	19-101	07-11-84			
FLUMETHASONE PIVALATE	0.03%	LOCORTEN	(CREAM; TOPICAL)	CIBA/CIBA-GEIGY	16-379	09-16-69	3499016	03-03-87	
FLUNISOLIDE	0.025MG/INH	BRONALIDE	(AEROSOL; INHALATION)	SYNTEX LABS/SYNTEX	18-340	08-17-84			NDF

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
FLUOCINONIDE 0.05%	LIDEX (SOLUTION; TOPICAL)	SYNTEX LABS/SYNTEX	18-849 04-06-84		NDF 09-24-86
FLUOCINONIDE 0.05%	VASODERM (CREAM; TOPICAL)	K-LINE PHARMS	19-117 06-26-84		
FLUPHENAZINE DECANOATE 25MG/ML	PROLIXIN DECANOATE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	16-727 06-20-72	3394131 07-23-85	
FLUPHENAZINE ENANTHATE 25MG/ML	PROLIXIN ENANTHATE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	16-110 03-15-67	3394131 07-23-85	
FLURANDRENOLIDE 0.004MG/SQ CM	CORDRAN (TAPE; TOPICAL)	DISTA PRODS/LILLY	16-455 07-29-69	3632740 01-04-89	
FLURAZEPAM HYDROCHLORIDE 15MG	DALMANE (CAPSULE; ORAL)	ROCHE PRODUCTS	16-721 04-07-70	4316897 02-23-99	
FLURAZEPAM HYDROCHLORIDE 30MG	DALMANE (CAPSULE; ORAL)	ROCHE PRODUCTS	16-721 04-07-70	4316897 02-23-99	
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	CHELSEA LABORATORIES	18-369 05-14-82		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	CHELSEA LABORATORIES	18-369 05-14-82		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	SUPERPHARM	18-370 02-10-83		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	SUPERPHARM	18-370 06-26-84		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-413 11-30-83		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-413 11-30-83		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-415 07-27-82		

STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NOA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY	EXP. DATE
FUROSEMIDE	40MG	FUROSEMIDE (TABLET; ORAL)	FEDERLE LABS/AM CYAN	18-415	07-27-82				
FUROSEMIDE	80MG	FUROSEMIDE (TABLET; ORAL)	FEDERLE LABS/AM CYAN	18-415	11-26-84				
FUROSEMIDE	20MG	FUROSEMIDE (TABLET; ORAL)	PARKE-DAVIS/W-L	18-419	01-31-83				
FUROSEMIDE	40MG	FUROSEMIDE (TABLET; ORAL)	PARKE-DAVIS/W-L	18-419	01-31-83				
FUROSEMIDE	80MG	FUROSEMIDE (TABLET; ORAL)	PARKE-DAVIS/W-L	18-419	11-13-84				
FUROSEMIDE	10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	PARKE-DAVIS/W-L	18-420	02-26-82				
FUROSEMIDE	10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	LYPHOMED	18-507	07-30-82				
FUROSEMIDE	80MG	FUROSEMIDE (TABLET; ORAL)	CORD LABORATORIES	18-569	08-14-84				
FUROSEMIDE	10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	NATCON	18-579	11-30-83				
FUROSEMIDE	10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-667	05-28-82				
FUROSEMIDE	10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	WYETH LABS/AMMO	18-670	07-20-82				
FUROSEMIDE	40MG	FUROSEMIDE (TABLET; ORAL)	DRUMMER/PHOENIX	18-750	07-30-84				
FUROSEMIDE	20MG	FUROSEMIDE (TABLET; ORAL)	INTL MEDICATION SYS	18-753	02-28-84				
FUROSEMIDE	40MG	FUROSEMIDE (TABLET; ORAL)	INTL MEDICATION SYS	18-753	02-28-84				

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	BARR LABORATORIES	18-790 11-29-83		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	ROXANE LABORATORIES	18-823 11-10-83		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	ROXANE LABORATORIES	18-823 11-10-83		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	KALAPHARM	18-868 06-28-83		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	KALAPHARM	18-868 06-28-83		
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	INVENEX LABS/LIFE	18-902 05-22-84		
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	INVENEX LABS/LIFE	19-036 08-13-84		
GEMFIBROZIL 200MG	LOPID (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-422 12-21-81	3674836 07-04-89	
GEMFIBROZIL 300MG	LOPID (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-422 12-21-81	3674836 07-04-89	
GLIPIZIDE 5MG	GLUCOTROL (TABLET; ORAL)	ROERIG/PFIZER	17-783 05-08-84	3669966 04-21-92	NCE 05-08-94
GLIPIZIDE 10MG	GLUCOTROL (TABLET; ORAL)	ROERIG/PFIZER	17-783 05-08-84	3669966 04-21-92	NCE 05-08-94
GLYBURIDE 1.25MG	MICRONASE (TABLET; ORAL)	UPJOHN	17-498 05-01-84	3426067 04-21-92 3454635 04-21-92 3507954 04-21-92 3507961 04-21-92	NCE 05-01-94

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
GLYBURIDE 2.5MG	MICRONASE (TABLET; ORAL)	UPJOHN	17-498	05-01-84	3426067 3454635 04-21-92 04-21-92 3507954 04-21-92 3507961 04-21-92	05-01-94	NCE	
GLYBURIDE 5MG	MICRONASE (TABLET; ORAL)	UPJOHN	17-498	05-01-84	3426067 3454635 04-21-92 04-21-92 3507954 04-21-92 3507961 04-21-92	05-01-94	NCE	
GLYBURIDE 1.25MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532	05-01-84	3426067 3454635 04-21-92 04-21-92 3507954 04-21-92 3507961 04-21-92	05-01-94	NCE	
GLYBURIDE 2.5MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532	05-01-84	3426067 3454635 04-21-92 04-21-92 3507954 04-21-92 3507961 04-21-92	05-01-94	NCE	

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
GLYBURIDE 5MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84	3426067 04-21-92 3454635 04-21-92 3507961 04-21-92 3507954 04-21-92 4060634 09-07-93	NCE 05-01-94
GONADORELIN HYDROCHLORIDE EQ 0.1MG BASE/VIAL	FACTREL (INJECTABLE; INJECTION)	AYERST LABS/AMHO	18-123 09-30-82	3947569 03-30-93 4110438 08-29-95	NCE 09-30-92
GONADORELIN HYDROCHLORIDE EQ 0.5MG BASE/VIAL	FACTREL (INJECTABLE; INJECTION)	AYERST LABS/AMHO	18-123 09-30-82	3947569 03-30-93 4110438 08-29-95	NCE 09-30-92
GONADOTROPIN, CHORIONIC 2,000 UNITS/VIAL	CHORIONIC GONADOTROPIN (INJECTABLE; INJECTION)	CARTER-GLOGAU LABS	17-016 12-27-84		
GONADOTROPIN, CHORIONIC 15,000 UNITS/VIAL	CHORIONIC GONADOTROPIN (INJECTABLE; INJECTION)	CARTER-GLOGAU LABS	17-016 02-15-84		
GUANABENZ ACETATE EQ 4MG BASE	WYTENSIN (TABLET; ORAL)	WYETH LABS/AMHO	18-587 09-07-82	3658993 04-25-89	NCE 09-07-92
GUANABENZ ACETATE EQ 8MG BASE	WYTENSIN (TABLET; ORAL)	WYETH LABS/AMHO	18-587 09-07-82	3658993 04-25-89	NCE 09-07-92
GUANADREL SULFATE 10MG	HYLOREL (TABLET; ORAL)	UPJOHN	18-104 12-29-82	3547951 12-15-87	NCE 12-29-92
GUANADREL SULFATE 25MG	HYLOREL (TABLET; ORAL)	UPJOHN	18-104 12-29-82	3547951 12-15-87	NCE 12-29-92

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
HALAZEPAM	20MG	PAXIPAM	(TABLET; ORAL)	SCHERING	17-736	09-24-81	3429874	02-25-86	
HALAZEPAM	40MG	PAXIPAM	(TABLET; ORAL)	SCHERING	17-736	09-24-81	3429874	02-25-86	
HALOPERIDOL	0.5MG	HALDOL	(TABLET; ORAL)	MCNEIL PHARM	15-921	04-12-67	3438991	04-15-86	
HALOPERIDOL	1MG	HALDOL	(TABLET; ORAL)	MCNEIL PHARM	15-921	04-12-67	3438991	04-15-86	
HALOPERIDOL	2MG	HALDOL	(TABLET; ORAL)	MCNEIL PHARM	15-921	04-12-67	3438991	04-15-86	
HALOPERIDOL	5MG	HALDOL	(TABLET; ORAL)	MCNEIL PHARM	15-921	04-16-74	3438991	04-15-86	
HALOPERIDOL	10MG	HALDOL	(TABLET; ORAL)	MCNEIL PHARM	15-921	04-16-74	3438991	04-15-86	
HALOPERIDOL	20MG	HALDOL	(TABLET; ORAL)	MCNEIL PHARM	15-921	04-16-74	3438991	04-15-86	
HALOPERIDOL LACTATE	EQ 2MG BASE/ML	HALDOL	(CONCENTRATE; ORAL)	MCNEIL LABORATORIES	15-922	04-12-67	3438991	04-15-86	
HALOPERIDOL LACTATE	EQ 5MG BASE/ML	HALDOL	(INJECTABLE; INJECTION)	MCNEIL LABORATORIES	15-923	05-18-71	3438991	04-15-86	
HEPARIN SODIUM	10 UNITS/ML	HEPARIN LOCK FLUSH	(INJECTABLE; INJECTION)	INVENEX LABS/LIFE	17-029	05-06-82			
HEPARIN SODIUM; SODIUM CHLORIDE	100 UNITS/ML; 4.5MG/ML	HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.45% (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	18-911	01-30-85			

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
HEPARIN SODIUM; SODIUM CHLORIDE 100 UNITS/ML; 4.5MG/ML	HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911 01-30-85		
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 200 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-042 03-29-85		
HEPARIN SODIUM; SODIUM CHLORIDE 200 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 1000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-609 04-28-82		

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
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HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911	01-30-85			
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916	01-31-84			
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 2500 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-135	03-29-85			
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916	01-31-84			
HEPARIN SODIUM; SODIUM CHLORIDE 1,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM; SODIUM CHLORIDE 1,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-042	03-29-85			
HEPARIN SODIUM; SODIUM CHLORIDE 1,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM; SODIUM CHLORIDE 1,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916	01-31-84			
HEPARIN SODIUM; SODIUM CHLORIDE 500 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM; SODIUM CHLORIDE 500 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-609	04-28-82			
HEPARIN SODIUM; SODIUM CHLORIDE 200 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM; SODIUM CHLORIDE 200 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 2000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-609	04-28-82			
HEPARIN SODIUM; SODIUM CHLORIDE 200 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM; SODIUM CHLORIDE 200 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 2000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-042	03-29-85			

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911 01-30-85		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911 01-30-85		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEXACHLOROPHENE 3%	TURGEX (SOLUTION; TOPICAL)	XTTRIUM LABS	19-055 11-30-84		
HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE 25MG; 50MG	LOPRESSOR HCT 50/25 (TABLET; ORAL)	GEIGY/CIBA-GEIGY	18-303 12-31-84	3876802 04-08-92 3998790 12-21-93	NC 12-31-87
HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE 25MG; 100MG	LOPRESSOR HCT 100/25 (TABLET; ORAL)	GEIGY/CIBA-GEIGY	18-303 12-31-84	3876802 04-08-92 3998790 12-21-93	NC 12-31-87
HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE 50MG; 100MG	LOPRESSOR HCT 100/50 (TABLET; ORAL)	GEIGY/CIBA-GEIGY	18-303 12-31-84	3876802 04-08-92 3998790 12-21-93	NC 12-31-87
HYDROCHLOROTHIAZIDE; TIMOLOL MALEATE 25MG; 10MG	TIMOLIDE (TABLET; ORAL)	MS&D/MERCK	18-061 12-11-81	3655663 04-11-89 4238485 12-09-97	
HYDROCHLOROTHIAZIDE; TRIAMTERENE 50MG; 75MG	MAXZIDE (TABLET; ORAL)	MYLAN PHARMS	19-129 10-22-84	4444769 04-24-01	NS 10-22-87

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY	EXP. DATE
HYDROCORTISONE ACETATE	10%	CORTIFOAM	(AEROSOL; RECTAL)	REED&CARBRICK PHARMS	17-351				NDF	09-24-86
HYDROCORTISONE BUTYRATE	0.1%	LOCOID	(CREAM; TOPICAL)	OWEN LABS/DERM PRODS	18-795				NP	09-24-86
HYDROCORTISONE BUTYRATE	0.1%	LOCOID	(TOPICAL)	OWEN LABS/DERM PRODS	19-106				NP	09-24-86
HYDROCORTISONE VALERATE	0.2%	WESTCORT	(TOPICAL)	WESTWOOD PHARMS	18-726				NDF	09-24-86
HYDROMORPHONE HYDROCHLORIDE	10MG/ML	DILAUDID-HP	(INJECTION)	KNOLL PHARMACEUTICAL	19-034				NCE	01-11-94
HYDROXYUREA	500MG	HYDREA	(CAPSULE; ORAL)	ER SQUIBB AND SONS	16-295		3968249	07-06-93		
IBUPROFEN	400MG	MOTRIN	(TABLET; ORAL)	UPJOHN MANUFACTURING	17-463				1-2	09-24-86
IBUPROFEN	300MG	MOTRIN	(TABLET; ORAL)	UPJOHN MANUFACTURING	17-463				1-2	09-24-86
IBUPROFEN	600MG	MOTRIN	(TABLET; ORAL)	UPJOHN MANUFACTURING	17-463				1-2	09-24-86
IBUPROFEN	400MG	RUFEN	(TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-197				1-2	09-24-86
IBUPROFEN	600MG	RUFEN	(TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-197				1-2	09-24-86
IBUPROFEN	2.5MG	LOZOL	(TABLET; ORAL)	USV PHARMACEUTICAL	18-538		3565911	02-23-88	NCE	07-06-93
INDOMETHACIN	50MG	INDOCIN	(SUPPOSITORY; RECTAL)	MS&D RES LABS/MERCK	17-814		3644630	02-22-89	NDF	09-24-86

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
INDOMETHACIN 75MG	INDOCIN SR (CAPSULE, CONTROLLED RELEASE; ORAL)	MS&D RES LABS/MERCK	18-185 02-23-82	4173626 11-06-96	NDF 09-24-86
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	CHELSEA LABORATORIES	18-690 07-31-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	CHELSEA LABORATORIES	18-690 07-31-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	ZENITH LABORATORIES	18-730 05-04-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	ZENITH LABORATORIES	18-730 05-04-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	PAR PHARMACEUTICAL	18-829 08-06-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	PAR PHARMACEUTICAL	18-829 08-06-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	18-851 05-18-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	18-851 05-18-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	MYLAN PHARMS	18-858 04-20-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	MYLAN PHARMS	18-858 04-20-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-806 11-23-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-806 11-23-84		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
INDOMETHACIN SODIUM TRIHYDRATE	EQ 1MG BASE/VIAL	INDOCIN I. V.	(INJECTABLE; INJECTION)	MS&D/HERCK	18-878	01-30-85			
IODAMIDE MEGLUMINE	24%	RENOVUE-DIP	(INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-903	07-10-78		09-24-86	1-6
IODAMIDE MEGLUMINE	65%	RENOVUE-65	(INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-902	07-24-78		09-24-86	1-6
IODOHIPPURATE SODIUM, I-123	1MCI/ML	NEPHROFLOW	(INJECTABLE; INJECTION)	MEDI-PHYSICS	18-289	12-28-84		12-28-89	NCE
IODOXAMATE MEGLUMINE	9.9%	CHOLUVE	(INJECTABLE; INJECTION)	ER SQUIBB AND SONS	18-076	08-14-81			
IODOXAMATE MEGLUMINE	40.3%	CHOLUVE	(INJECTABLE; INJECTION)	ER SQUIBB AND SONS	18-077	08-14-81			
ISOFLURANE	99.9%	FORANE	(GAS; INHALATION)	ANAQUEST/BOC	17-624	12-18-79			
ISOTRETINOIN	10MG	ACCUTANE	(CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662	05-07-82		05-07-92	NCE
ISOTRETINOIN	20MG	ACCUTANE	(CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662	03-28-83		05-07-92	NCE

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
ISOTRETINOIN 40MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 05-07-82	4200647 04-29-97 4322438 03-30-99 4464394 08-07-01	NCE 05-07-92
KETOCONAZOLE 200MG	NIZORAL (TABLET; ORAL)	JANSSEN PHARMA	18-533 06-12-81	4335125 06-15-99	I-25 09-24-86
LABETALOL HYDROCHLORIDE 200MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-687 08-01-84	4012444 03-15-94 4006755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 300MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-687 08-01-84	4012444 03-15-94 4006755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 400MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-687 08-01-84	4012444 03-15-94 4006755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 5MG/ML	NORMODYNE (INJECTABLE; INJECTION)	SCHERING	18-686 08-01-84	4012444 03-15-94 4006755 01-03-95 4328213 05-04-99	NCE 08-01-94
LABETALOL HYDROCHLORIDE 200MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84	4012444 03-15-94 4006755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 300MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84	4012444 03-15-94 4006755 01-03-95	NCE 08-01-94

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
LABETALOL HYDROCHLORIDE	400MG	TRANDATE	(TABLET; ORAL)	GLAXO	18-716	08-01-84	4012444	03-15-94	NCE
LACTULOSE	10GM/15ML	CEPHULAC	(SYRUP; ORAL)	MERRELL DOW/DOW CHEM	17-657	03-25-76	3461204	08-12-86	
							3867524	02-18-92	
							02-18-92	3860708	
							01-14-92	3860707	
							01-14-92	3562388	
							02-09-88	3558774	
							01-26-88		
LEUCOVORIN CALCIUM	EQ 5MG BASE	WELLCOVORIN	(TABLET; ORAL)	BURROUGHS WELLCOME	18-342	07-08-83			NDF
LEUCOVORIN CALCIUM	EQ 25MG BASE	WELLCOVORIN	(TABLET; ORAL)	BURROUGHS WELLCOME	18-342	07-08-83			NDF
LEUPROLIDE ACETATE	1MG/0.2ML	LUPRON	(INJECTABLE; INJECTION)	TAP PHARMACEUTICALS	19-010	04-09-85			NCE
LITHIUM CARBONATE	450MG	ESKALITH CR	(TABLET, CONTROLLED RELEASE; ORAL)	SK&F LABORATORIES	18-152	03-29-82			NS
LITHIUM CARBONATE	300MG	LITHIUM CARBONATE	(TABLET; ORAL)	ROXANE LABORATORIES	18-558	01-29-82			
LITHIUM CARBONATE	300MG	LITHIUM CARBONATE	(TABLET; ORAL)	CIBA/CIBA-GEIGY	18-027	04-27-79			
LOPERAMIDE HYDROCHLORIDE	2MG	IMODIUM	(CAPSULE; ORAL)	JANSSEN PHARMA	17-694	12-28-76			I-30
							3714159	01-30-90	
							4264573	04-28-98	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
LOPERAMIDE HYDROCHLORIDE 1MG/5ML	IMODIUM (SOLUTION; ORAL)	JANSSEN PHARMA	19-037 07-31-84	3714159 01-30-90	NDF 09-24-86
LOXAPINE HYDROCHLORIDE EQ 50MG BASE/ML	LOXITANE (INJECTABLE; INJECTION)	LEDERLE LABS/AM CYAN	18-039 10-26-79	3546226 12-08-87	
LOXAPINE HYDROCHLORIDE EQ 25MG BASE/ML	LOXITANE (CONCENTRATE; ORAL)	LEDERLE LABS/AM CYAN	17-658 05-04-76	3546226 12-08-87 4049809 09-20-94	
LOXAPINE SUCCINATE EQ 5MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 10-25-77	3546226 12-08-87	
LOXAPINE SUCCINATE EQ 10MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 02-25-75	3546226 12-08-87	
LOXAPINE SUCCINATE EQ 25MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 02-25-75	3546226 12-08-87	
LOXAPINE SUCCINATE EQ 50MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 02-25-75	3546226 12-08-87	
MAFENIDE ACETATE EQ 85MG BASE/GM	SULFAMYLLON (CREAM; TOPICAL)	WINTHROP LABS/STERL	16-763 01-24-69	3497599 01-26-88	
MAGNESIUM ACETATE TETRAHYDRATE; POTASSIUM ACETATE; SODIUM CHLORIDE 32MG/100ML; 128MG/100ML; 234MG/100ML	PLASMA-LYTE 56 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-047 06-15-84		NC 09-24-86
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE 30MG/100ML; 37MG/100ML; 0.82MG/100ML; 370MG/100ML; 530MG/100ML; 500MG/100ML; 12MG/100ML	ISOLYTE PH 7.4 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-006 04-04-84		NC 09-24-86

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	526MG/100ML; 37MG/100ML; 222MG/100ML; 30MG/100ML; 502MG/100ML	PHYSIO-SOL IN PLASTIC CONTAINER	(SOLUTION; IRRIGATION)	ABBOTT LABORATORIES	17-637	07-08-82		09-24-86	NC
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	526MG/100ML; 37MG/100ML; 222MG/100ML; 30MG/100ML; 502MG/100ML	PHYSIO-SOL IN PLASTIC CONTAINER	(SOLUTION; IRRIGATION)	ABBOTT LABORATORIES	18-406	07-08-82		09-24-86	NC
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	526MG/100ML; 37MG/100ML; 222MG/100ML; 30MG/100ML; 502MG/100ML	PHYSIO-SOL IN PLASTIC CONTAINER	(SOLUTION; IRRIGATION)	AM MCGAW/AM HOSP	19-024	06-08-84		09-24-86	NC
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	526MG/100ML; 37MG/100ML; 368MG/100ML; 526MG/100ML; 502MG/100ML	SYNALYTE IN PLASTIC CONTAINER	(SOLUTION; IRRIGATION)	TRAVENOL LABS	19-326	01-25-85			
MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE; MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE	20MG/100ML; 40MG/100ML; 6.25MG/100ML; 800MG/100ML; 8.75MG/100ML	TIS-U-SOL	(SOLUTION; IRRIGATION)	TRAVENOL LABS	18-508	02-19-82		09-24-86	NC
MALATHION	0.5%	PRIDERM	(LOTION; TOPICAL)	PURDUE FREDERICK	18-613	08-02-82			NCE
MAPPOTILINE HYDROCHLORIDE	25MG	LUDIOMIL (TABLET; ORAL)		CIBA/CIBA-GEIGY	17-543	12-01-80		08-27-85	3399201
MAPPOTILINE HYDROCHLORIDE	50MG	LUDIOMIL (TABLET; ORAL)		CIBA/CIBA-GEIGY	17-543	12-01-80		08-27-85	3399201

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
MAPROTILINE HYDROCHLORIDE 75MG	LUDIOMIL (TABLET; ORAL)	CIBA/CIBA-GEIGY	17-543 09-30-82	3399201 08-27-85	NS 09-24-86
MAZINDOL 1MG	SANOREX (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	17-247 06-14-73	3763178 10-02-90	
MAZINDOL 2MG	SANOREX (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	17-247 06-14-73	3763178 10-02-90	
MAZINDOL 2MG	MAZANOR (TABLET; ORAL)	WYETH LABS/AMHO	17-980 08-28-80	3763178 10-02-90	
MAZINDOL 1MG	MAZANOR (TABLET; ORAL)	WYETH LABS/AMHO	17-980 02-02-82	3763178 10-02-90	
MEBENDAZOLE 100MG	VERMOX (TABLET, CHEWABLE; ORAL)	JANSSEN PHARMA	17-481 06-28-74	3657267 04-18-89	
MEDROXYPROGESTERONE ACETATE 100MG/ML	DEPO-PROVERA (INJECTABLE; INJECTION)	UPJOHN	12-541 01-16-76	4038389 07-26-94	
MEDROXYPROGESTERONE ACETATE 400MG/ML	DEPO-PROVERA (INJECTABLE; INJECTION)	UPJOHN	12-541 01-16-76	4038389 07-26-94	
MEGLUMINE; METRIZOIC ACID 140.1MG/ML; 461.8MG/ML	ISOPAQUE-280 (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-506 04-30-74	3476802 11-04-86	
METAPROTERENOL SULFATE 20MG	ALUPENT (TABLET; ORAL)	BOEHRINGER INGELHEIM	15-874 05-13-74	3422196 01-14-86	
METAPROTERENOL SULFATE 10MG	ALUPENT (TABLET; ORAL)	BOEHRINGER INGELHEIM	15-874 08-08-77	3422196 01-14-86	
METAPROTERENOL SULFATE 0.65MG/INH	ALUPENT (AEROSOL; INHALATION)	BOEHRINGER INGELHEIM	16-402 07-31-73	3422196 01-14-86	
METAPROTERENOL SULFATE 10MG/5ML	ALUPENT (SYRUP; ORAL)	BOEHRINGER INGELHEIM	17-571 05-23-75	3422196 01-14-86	
METAPROTERENOL SULFATE 5%	ALUPENT (SOLUTION; INHALATION)	BOEHRINGER INGELHEIM	17-659 09-18-80	3422196 01-14-86	
METAPROTERENOL SULFATE 0.6%	ALUPENT (SOLUTION; INHALATION)	BOEHRINGER INGELHEIM	18-761 06-30-83	3422196 01-14-86	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
METHYLDOPA	250MG	METHYLDOPA	(TABLET; ORAL)	CORD LABORATORIES	18-934	06-29-84			
METHYLDOPA	500MG	METHYLDOPA	(TABLET; ORAL)	CORD LABORATORIES	18-934	06-29-84			
METHYLDOPA	250MG/5ML	ALDOMET	(SUSPENSION; ORAL)	MS&D/MERCK	18-389	08-28-81	4404193	09-13-00	
METHYLDOPA	250MG	RITALIN-SR	(TABLET, CONTROLLED RELEASE; ORAL)	CIBA/CIBA-GEIGY	18-029	03-30-82			NDF
METOCLOPRAMIDE	EQ 5MG BASE/5ML	REGLAN	(SYRUP; ORAL)	AH ROBIN	18-821	3-25-83			NDF
METOCLOPRAMIDE HYDROCHLORIDE	EQ 5MG BASE/5ML	REGLAN	(INJECTABLE; INJECTION)	AH ROBIN	17-862	02-07-79			1-12; 1-13; 09-24-86
METOCLOPRAMIDE HYDROCHLORIDE	EQ 10MG BASE	REGLAN	(TABLET; ORAL)	AH ROBIN	17-854	12-30-80			1-4 09-24-86
METOPROLOL TARTRATE	50MG	LOPRESSOR	(TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-963	08-07-78	3876802	04-08-92	NDF
METOPROLOL TARTRATE	100MG	LOPRESSOR	(TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-963	08-07-78	3876802	04-08-92	NDF
METOPROLOL TARTRATE	1MG/ML	LOPRESSOR	(INJECTABLE; INJECTION)	GEIGY/CIBA-GEIGY	18-704	03-30-84	3876802	04-08-92	NDF

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METRIZAMIDE 3.75GM/VIAL	AMIPAQUE (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-982 08-23-78	3701771 10-31-89	I-26 09-24-86
METRIZAMIDE 6.75GM/VIAL	AMIPAQUE (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-982 08-23-78	3701771 10-31-89	I-26 09-24-86
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	ZENITH LABORATORIES	18-517 05-05-82		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	CHELSEA LABORATORIES	18-599 09-17-82		
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	CHELSEA LABORATORIES	18-599 02-13-84		
METRONIDAZOLE 250MG	METRYL (TABLET; ORAL)	DRUMMER/PHOENIX	18-620 03-04-82		
METRONIDAZOLE 500MG	METRYL 500 (TABLET; ORAL)	DRUMMER/PHOENIX	18-620 06-02-83		
METRONIDAZOLE 500MG/100ML	METRO I.V. (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-674 08-31-82		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	CORD LABORATORIES	18-740 10-22-82		
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	CORD LABORATORIES	18-740 10-22-82		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	DANBURY PHARMACAL	18-764 09-17-82		
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	DANBURY PHARMACAL	18-764 12-20-82		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	BARR LABORATORIES	18-818 02-16-83		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
METRONIDAZOLE	500MG	METRONIDAZOLE	(TABLET; ORAL)	BARR LABORATORIES	18-818	02-16-83	18-845	08-18-83	
METRONIDAZOLE	250MG	METRONIDAZOLE	(TABLET; ORAL)	PAR PHARMACEUTICAL	18-845	08-18-83	18-871	03-02-83	
METRONIDAZOLE	250MG	PROTOSTAT	(TABLET; ORAL)	ORTHO PHARMACEUTICAL	18-871	03-02-83	18-871	03-02-83	
METRONIDAZOLE	500MG	PROTOSTAT	(TABLET; ORAL)	ORTHO PHARMACEUTICAL	18-871	03-02-83	18-889	11-18-83	
METRONIDAZOLE	500MG/100ML	METRONIDAZOLE IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-890	11-18-83	18-890	11-18-83	
METRONIDAZOLE	500MG/100ML	METRO I.V. IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	AM HCGAM/AM HOSP	18-900	09-29-83	18-907	03-30-84	
METRONIDAZOLE	500MG/100ML	METRONIDAZOLE	(INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-907	03-30-84	18-353	05-29-81	
METRONIDAZOLE	500MG/100ML	FLAGYL I.V. RTU	(INJECTABLE; INJECTION)	SEARLE PHARMS	18-353	05-29-81	18-657	12-24-81	
METRONIDAZOLE	500MG/100ML	FLAGYL I.V. RTU IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	SEARLE PHARMS	18-657	12-24-81	18-930	08-18-83	
METRONIDAZOLE	500MG	METRONIDAZOLE	(TABLET; ORAL)	PAR PHARMACEUTICAL	18-930	08-18-83	19-029	04-10-84	
METRONIDAZOLE	250MG	METRONIDAZOLE	(TABLET; ORAL)	LNK INTERNATIONAL	19-029	04-10-84			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
METRONIDAZOLE HYDROCHLORIDE EQ 500MG BASE/VIAL	FLAGYL I.V. (INJECTABLE; INJECTION)	SEARLE PHARMS	18-353 11-28-80		I-11 12-20-87
MICONAZOLE 10MG/ML	MONISTAT (INJECTABLE; INJECTION)	JANSSEN PHARMA	18-040 10-04-78	3717655 02-20-90 3839574 10-01-91	I-27 09-24-86
MICONAZOLE NITRATE 2%	MONISTAT 7 (CREAM; VAGINAL)	ORTHO PHARMACEUTICAL	17-450 01-30-74	3717655 02-20-90 3839574 10-01-91	
MICONAZOLE NITRATE 2%	MONISTAT-DERM (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-494 01-30-74	3717655 02-20-90 3839574 10-01-91	
MICONAZOLE NITRATE 2%	MONISTAT-DERM (LOTION; TOPICAL)	ORTHO PHARMACEUTICAL	17-739 12-16-75	3717655 02-20-90 3839574 10-01-91	
MICONAZOLE NITRATE 100MG	MONISTAT 7 (SUPPOSITORY; VAGINAL)	ORTHO PHARMACEUTICAL	18-520 03-15-82	3717655 02-20-90 3839574 10-01-91	NDF 9-24-86
MICONAZOLE NITRATE 200MG	MONISTAT 3 (SUPPOSITORY; VAGINAL)	ORTHO PHARMACEUTICAL	18-888 08-15-84	3717655 02-20-90 3839574 10-01-91	NS 09-24-86
MINOXIDIL 2.5MG	LONITEN (TABLET; ORAL)	UPJOHN	18-154 10-18-79	3461461 08-12-86	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
MINOXIDIL	10MG	LONITEN	(TABLET; ORAL)	UPJOHN	18-154	08-12-86	3461461		
MOLINDONE HYDROCHLORIDE	5MG	MOBAN	(TABLET; ORAL)	DUPONT PHARMS/DUPONT	17-111	01-20-87	3491093		
MOLINDONE HYDROCHLORIDE	10MG	MOBAN	(TABLET; ORAL)	DUPONT PHARMS/DUPONT	17-111	07-03-74	3491093		
MOLINDONE HYDROCHLORIDE	25MG	MOBAN	(TABLET; ORAL)	DUPONT PHARMS/DUPONT	17-111	07-03-74	3491093		
MOLINDONE HYDROCHLORIDE	50MG	MOBAN	(TABLET; ORAL)	DUPONT PHARMS/DUPONT	17-111	01-05-81	3491093		
MOLINDONE HYDROCHLORIDE	100MG	MOBAN	(TABLET; ORAL)	DUPONT PHARMS/DUPONT	17-111	01-05-81	3491093		
MOLINDONE HYDROCHLORIDE	20MG/ML	MOBAN	(CONCENTRATE; ORAL)	DUPONT PHARMS/DUPONT	17-938	12-28-79	3491093		
MORPHINE SULFATE	0.5MG/ML	DURAMORPH PF	(INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-565	09-18-84			NR: D-8 09-24-86
MORPHINE SULFATE	1MG/ML	DURAMORPH PF	(INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-565	09-18-84			NR: D-8 09-24-86
MAOULO	40MG	CORGARD	(TABLET; ORAL)	ER SQUIBB AND SONS	18-063	12-10-79	3982021		
MAOULO	80MG	CORGARD	(TABLET; ORAL)	ER SQUIBB AND SONS	18-063	12-10-79	3982021		
MAOULO	120MG	CORGARD	(TABLET; ORAL)	ER SQUIBB AND SONS	18-063	12-10-79	3982021		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
NADOLOL 160MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-063 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 40MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 80MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 120MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 160MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NALBUPHINE HYDROCHLORIDE 10MG/ML	NUBAIN (INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	18-024 05-15-79	3393197 07-16-85	
NALBUPHINE HYDROCHLORIDE 20MG/ML	NUBAIN (INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	18-024 05-27-82		NS 09-24-86
NALIDIXIC ACID 250MG	NEGGRAM (TABLET; ORAL)	WINTHROP LABS/STERL	14-214 12-27-67	3590036 06-29-88	
NALIDIXIC ACID 500MG	NEGGRAM (TABLET; ORAL)	WINTHROP LABS/STERL	14-214 03-06-64	3590036 06-29-88	
NALIDIXIC ACID 1GM	NEGGRAM (TABLET; ORAL)	WINTHROP LABS/STERL	14-214 03-06-64	3590036 06-29-88	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	PATENT NO.	EXP. DATE
NALIDIXIC ACID	250MG/5ML	MEGGRAH	(SUSPENSION; ORAL)	WINTHROP LABS/STERL	17-430	3590036	06-29-88
NALOXONE HYDROCHLORIDE	0.4MG/ML	NARCAN	(INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	16-636		04-13-71
NALOXONE HYDROCHLORIDE	1MG/ML	NARCAN	(INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	16-636		06-14-82
NALOXONE HYDROCHLORIDE; PENTAZOCINE	0.5MG; EQ 50MG BASE HYDROCHLORIDE	TALWIN NX	(TABLET; ORAL)	WINTHROP LABS/STERL	18-733	4105659	08-08-95
NALTREXONE HYDROCHLORIDE	50MG	TREXAN	(TABLET; ORAL)	DUPONT PHARMS/DUPONT	18-932		11-20-84
NAPROXEN	125MG	NAPROSYN	(TABLET; ORAL)	SYNTEX PR	17-581	3904682	09-09-92
NAPROXEN	250MG	NAPROSYN	(TABLET; ORAL)	SYNTEX PR	17-581	3904682	09-09-92

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
NAPROXEN 375MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17-581 07-18-80	3904682 09-09-92 3998966 12-21-93 4001301 09-09-92 4009197 09-09-92	
NAPROXEN 500MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17-581 04-15-82	3904682 09-09-92 3998966 12-21-93 4001301 09-09-92 4009197 09-09-92	NS 09-24-86
NAPROXEN SODIUM 275MG	ANAPROX (TABLET; ORAL)	SYNTEX PR	18-164 09-04-80	3998966 12-21-93 4001301 09-09-92 4009197 09-09-92	
NICLOSAMIDE 500MG	NICLOCIDE (TABLET, CHEWABLE; ORAL)	MILES PHARMS/MILES	18-669 05-14-82		NCE 05-14-92
NICOTINE RESIN COMPLEX EQ 2MG BASE	NICORETTE (GUM, CHEWING; ORAL)	MERRELL DOW/DOW CHEM	18-612 01-13-84		NCE 01-13-94
NIFEDIPINE 10MG	PROCARDIA (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-482 12-31-81	3644627 02-22-89	
NITROGLYCERIN 0.5MG/ML	TRIDIL (INJECTABLE; INJECTION)	AM CRITICAL CARE/AHS	18-537 06-16-83		NDF 09-24-86
NITROGLYCERIN 5MG/ML	NITROSTAT (INJECTABLE; INJECTION)	PARKE-DAVIS/W-L	18-588 12-23-83		NDF 09-24-86

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
NITROGLYCERIN	5MG/ML	NITRO-BID	(INJECTABLE; INJECTION)	MARION LABORATORIES	18-621	01-05-82		09-24-86	NDF
NITROGLYCERIN	1MG/ML	NITRONAL	(INJECTABLE; INJECTION)	G POHL-BOSKAMP	18-672	08-30-83		09-24-86	NDF
NITROGLYCERIN	5MG/ML	NITRONAL	(INJECTABLE; INJECTION)	G POHL-BOSKAMP	18-672	08-30-83		09-24-86	NDF
NITROGLYCERIN	0.8MG/ML	NITROL	(INJECTABLE; INJECTION)	KREMERS-URBAN	18-774	01-19-83		09-24-86	NDF
NOMIFENSINE MALEATE	25MG	MERITAL	(CAPSULE; ORAL)	HOECHST-ROUSSEL	18-224	12-31-84		12-31-89	NCE
NOMIFENSINE MALEATE	50MG	MERITAL	(CAPSULE; ORAL)	HOECHST-ROUSSEL	18-224	12-31-84		12-31-89	NCE
NORETHINDRONE ACETATE	5MG	AVGESTIN	(TABLET; ORAL)	AYERST LABS/AMHO	18-405	04-21-82			
MORGESTREL	0.075MG	OVARETTE	(TABLET; ORAL)	WYETH LABS/AMHO	17-031	10-23-73			
NORFLOXYLINE HYDROCHLORIDE	EQ 10MG BASE	AVENTYL HCL	(CAPSULE; ORAL)	ELI LILLY	14-684	11-06-64		3922305	
NORFLOXYLINE HYDROCHLORIDE	EQ 25MG BASE	AVENTYL HCL	(CAPSULE; ORAL)	ELI LILLY	14-684	11-06-64		3922305	
NORFLOXYLINE HYDROCHLORIDE	EQ 10MG BASE/5ML	AVENTYL HCL	(SOLUTION; ORAL)	ELI LILLY	14-685	11-06-64		3922305	
NORFLOXYLINE HYDROCHLORIDE	EQ 10MG BASE/5ML	PAMELOR	(SOLUTION; ORAL)	SANDOZ PHARMS/SANDOZ	18-012	08-01-77		39222305	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 08-01-77	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 25MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 08-01-77	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 75MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 06-14-79	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 50MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 06-14-79	3922305 11-25-92	
OXAMNIQUINE 250MG	VANSIL (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-069 07-23-80	3903283 09-02-92 3821228 06-28-91 3925391 12-09-92	
OXPRENOLOL HYDROCHLORIDE 20MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93
OXPRENOLOL HYDROCHLORIDE 40MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93
OXPRENOLOL HYDROCHLORIDE 80MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93
OXPRENOLOL HYDROCHLORIDE 160MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93
PANCURONIUM BROMIDE 2MG/ML	PAVULON (INJECTABLE; INJECTION)	ORGANON/AKZONA	17-015 10-24-72	3553212 01-05-88	
PANCURONIUM BROMIDE 1MG/ML	PAVULON (INJECTABLE; INJECTION)	ORGANON/AKZONA	17-015 09-14-73	3553212 01-05-88	
PARAMETHASONE ACETATE 1MG	HALDRONE (TABLET; ORAL)	ELI LILLY	12-772 04-17-61	3499016 03-03-87	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
PARAMETHASONE ACETATE	2MG	HALDRONE	(TABLET; ORAL)	ELI LILLY	12-772	03-03-87	3499016		
PENTAGASTRIN	0.25MG/ML	PEPTAVLON	(INJECTABLE; INJECTION)	AYERST LABS/AMHO	17-048	07-26-74	3896103		
PENTAMIDINE ISETHIONATE	300MG/VIAL	PENTAM 300	(INJECTABLE; INJECTION)	LYPHOMED	19-264	10-16-84			
PENTAZOCINE LACTATE	EQ 30MG BASE/ML	TALWIN	(INJECTABLE; INJECTION)	WINTHROP LABS/STERL	16-194	07-24-67	4105659		
PENTETATE INDIUM DISODIUM, IN-111	IMCI/ML	MPI INDIUM DTPA IN 111	(INJECTABLE; INJECTION)	MEDI-PHYSICS	17-707	02-18-82			
PENTOXIFYLLINE	400MG	TRENTAL	(TABLET, CONTROLLED RELEASE; ORAL)	HOECHST-ROUSSEL	18-631	08-30-84	3737433		
PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE	5MG/5ML; 6.25MG/5ML	PHENERGAN VC	(SYRUP; ORAL)	WYETH LABS/AMHO	08-604	04-02-84			
PILLOCARPINE HYDROCHLORIDE	4%	PILOPINE HS	(GEL; OPHTHALMIC)	ALCON LABORATORIES	18-796	10-01-84			
PIMOZIDE	2MG	ORAP	(TABLET; ORAL)	MCNEIL PHARM	17-473	07-31-84			
PINDOLOL	5MG	VISKEN	(TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	18-285	09-03-82	3471515		

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
PINDOLOL 10MG	VISKEN (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	18-285 09-03-82	3471515 10-07-86	NCE 09-03-92
PINDOLOL 15MG	VISKEN (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	18-285 09-03-82	3471515 10-07-86	NCE 09-03-92
PIROXICAM 10MG	FELDENE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-147 04-06-82	3591584 07-06-88 3674876 07-04-89 3862319 01-21-92 4100347 07-11-95 3927002 12-16-92 RE29668 12-10-91	NCE 04-06-92
PIROXICAM 20MG	FELDENE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-147 04-06-82	3591584 07-06-88 3674876 07-04-89 3862319 01-21-92 4100347 07-11-95 3927002 12-16-92 RE29668 12-10-91	NCE 04-06-92
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE 23.6GM/BOT; 2.97GM/BOT; 6.74GM/BOT; 5.86GM/BOT; 22.74GM/BOT	GOLYTEL (POWDER FOR RECONSTITUTION; ORAL)	BRAINTREE LABS	19-011 07-13-84		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE; 120GM/PACKET; 1.49GM/PACKET; 3.36GM/PACKET; 2.92GM/PACKET; 11.36GM/PACKET		COLYTE	(POWDER FOR RECONSTITUTION; ORAL)	EDLAW PREPARATIONS	18-983	10-26-84			
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE; 227.1GM/PACKET; 2.82GM/PACKET; 6.36GM/PACKET; 5.53GM/PACKET; 21.5GM/PACKET		COLYTE	(POWDER FOR RECONSTITUTION; ORAL)	EDLAW PREPARATIONS	18-983	10-26-84			
POLYETHYLENE GLYCOL 3350; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE; SODIUM CHLORIDE; 2.08GM/PACKET; 4.47GM/PACKET; 10.08GM/PACKET; 8.76GM/PACKET; 34.08GM/PACKET		MINIZIDE	(CAPSULE; ORAL)	Pfizer Labs/Pfizer	17-986	06-13-80			3511836 05-12-87 3663706 05-16-89 4130647 12-19-95

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE 0.5MG; 2MG	MINIZIDE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-986 06-13-80	3511836 05-12-87 3663706 05-16-89 4130647 12-19-95	
POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE 0.5MG; 5MG	MINIZIDE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-986 06-13-80	3511836 05-12-87 3663706 05-16-89 4130647 12-19-95	
POTASSIUM ACETATE 2MEQ/ML	POTASSIUM ACETATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-896 07-20-84		NDF 09-24-86
POTASSIUM CHLORIDE 10MEQ	KLOTRIX (TABLET, CONTROLLED RELEASE; ORAL)	MEAD JOHNSON/B-M	17-850 05-22-80	4140756 02-20-96	
POTASSIUM CHLORIDE; SODIUM CHLORIDE 150MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 300MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 150MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 300MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	DOSEAGE FORM, ROUTE	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
POTASSIUM CHLORIDE; SODIUM CHLORIDE	75MG/100ML; 900MG/100ML		SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722	11-09-82			
POTASSIUM CHLORIDE; SODIUM CHLORIDE	150MG/100ML; 900MG/100ML		SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722	11-09-82			
POTASSIUM CHLORIDE; SODIUM CHLORIDE	220MG/100ML; 900MG/100ML		SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722	11-09-82			
POTASSIUM CHLORIDE; SODIUM CHLORIDE	300MG/100ML; 900MG/100ML		SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722	11-09-82			
PRALIDOXIME CHLORIDE	300MG/ML		PROTOPAM CHLORIDE (INJECTABLE; INJECTION)	AVERST LABS/AMMO	18-799	12-13-82			NDF
PRALIDOXIME CHLORIDE	300MG/ML		PRALIDOXIME CHLORIDE (INJECTABLE; INJECTION)	SURVIVAL TECHNOLOGY	18-986	12-13-82			NDF
PARAZEPAM	20MG	CENTRAX	(CAPSULE; ORAL)	PARKER-DAVIS/W-L	18-144	05-10-82			NS
PRATIQUANTEL	600MG	BILTRICIDE	(TABLET; ORAL)	MILES PHARMS/MILES	18-714	12-29-82			NCE
PRADOXIN HYDROCHLORIDE	5MG	MINIPRESS	(CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-442	06-23-76			
					3511836	05-12-87	3663706	05-16-89	
					4092315	05-30-95	4130647	12-19-95	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
PRazosin HYDROCHLORIDE 1MG	MINIPRESS (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-442 06-23-76	3511836 05-12-87 3663706 05-16-89 4092315 05-30-95 4130647 12-19-95	
PRazosin HYDROCHLORIDE 2MG	MINIPRESS (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-442 06-23-76	3511836 05-12-87 3663706 05-16-89 4092315 05-30-95 4130647 12-19-95	
PROBUCOL 250MG	LORELCO (TABLET; ORAL)	MERRELL DOW/DOW CHEM	17-535 02-01-77	3576883 04-27-88 3862332 01-21-92	
PROCARBAZINE HYDROCHLORIDE EQ 50MG BASE	MATULANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	16-785 07-22-69	3520926 07-21-87	
PROPRANOLOL HYDROCHLORIDE 10MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 11-13-67		I-15 09-24-86
PROPRANOLOL HYDROCHLORIDE 20MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 10-16-74		I-15 09-24-86
PROPRANOLOL HYDROCHLORIDE 40MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 11-13-67		I-15 09-24-86
PROPRANOLOL HYDROCHLORIDE 60MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 10-18-82		NS 09-24-86
PROPRANOLOL HYDROCHLORIDE 80MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 10-16-74		I-15 09-24-86

STRENGTH(S)	ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY	EXP. DATE
80MG	PROPRANOLOL HYDROCHLORIDE	INDERAL LA	(CAPSULE; CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553	04-19-83		09-24-86	NDF	
90MG	PROPRANOLOL HYDROCHLORIDE	INDERAL (TABLET; ORAL)		AYERST LABS/AMHO	16-418	10-18-82		09-24-86	NS	
120MG	PROPRANOLOL HYDROCHLORIDE	INDERAL LA (CAPSULE; CONTROLLED RELEASE; ORAL)		AYERST LABS/AMHO	18-553	04-19-83		09-24-86	NDF	
160MG	PROPRANOLOL HYDROCHLORIDE	INDERAL LA (CAPSULE; CONTROLLED RELEASE; ORAL)		AYERST LABS/AMHO	18-553	04-19-83		09-24-86	NDF	
5%	PROTEIN HYDROLYSATE	AMINOSOL 5% (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	05-932	01-31-85			NS	
250MG/VIAL	PROTAMINE SULFATE	PROTAMINE SULFATE (INJECTABLE; INJECTION)		UPJOHN	07-413	08-02-84				
0.5MG/ML	PROTIRELIN	THYPINONE (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	17-638	11-05-76		07-17-90		
0.5MG/ML	PROTIRELIN	RELFACT TRM (INJECTABLE; INJECTION)		HOECHST-ROUSSEL	18-087	07-18-78		07-17-90		
EQ 250MG BASE/5ML	PYRANTEL PAMOATE	ANTIMINTH (SUSPENSION; ORAL)		ROERIG/PFIZER	16-883	12-30-71		02-22-89		
EQ 150MG BASE	RANITIDINE HYDROCHLORIDE	ZANTAC (TABLET; ORAL)		GLAXO	18-703	06-09-83		12-05-95	NCE	06-09-93
EQ 25MG BASE/ML	RANITIDINE HYDROCHLORIDE	ZANTAC (INJECTION)		GLAXO	19-090	10-19-84		12-05-95	NCE	06-09-93

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
RITODRINE HYDROCHLORIDE 10MG	YUTOPAR (TABLET; ORAL)	ASTRA PHARM PRODS	18-555 12-12-80	3410944 11-12-85	
RITODRINE HYDROCHLORIDE 10MG/ML	YUTOPAR (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-580 12-12-80	3410944 11-12-85	
RITODRINE HYDROCHLORIDE 15MG/ML	YUTOPAR (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-580 09-27-84	3410944 11-12-85	
SAFFLOWER OIL; SOYBEAN OIL 10%; 10%	LIPOSYN II 20% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-991 08-27-84		NP 09-24-86
SAFFLOWER OIL; SOYBEAN OIL 5%; 5%	LIPOSYN II 10% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-997 08-27-84		NP 09-24-86
SARALASIN ACETATE EQ 0.6MG BASE/ML	SARENIN (INJECTABLE; INJECTION)	NORWICH EATON/P&G	18-009 05-29-81	3932624 01-13-93 3886134 05-27-92	
SCOPOLAMINE 1.5MG	TRANSDERM-SCOP (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	CIBA/CIBA-GEIGY	17-874 12-31-79	4031894 06-28-94 4262003 04-14-98 4436741 04-14-98	
SELENIUM SULFIDE 2.5%	SELSUN (SHAMPOO/LOTION; TOPICAL)	ABBOTT LABS	07-936 05-17-51		I-3 09-24-86
SILVER SULFADIAZINE 1%	SILVADENE (CREAM; TOPICAL)	MARION LABORATORIES	17-381 11-26-73	3761590 09-24-90	
SILVER SULFADIAZINE 1%	SSD (CREAM; TOPICAL)	TRAVENOL LABS	18-578 02-25-82		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
SINCALIDE	0.005MG/VIAL	KINEVAC	(INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-697	07-21-76	3839315	10-01-91	
SODIUM ACETATE, ANHYDROUS	2MEQ/ML	SODIUM ACETATE IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-893	05-04-83			PP
SODIUM CHLORIDE	450MG/100ML	SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)		TRAVENOL LABS	18-497	02-19-82			
SODIUM CHLORIDE	9MG/ML	BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	18-800	10-29-82			
SODIUM CHLORIDE	9MG/ML	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	18-803	10-29-82			
SODIUM CHLORIDE	2.5MEQ/ML	SODIUM CHLORIDE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	18-897	07-20-84			
SODIUM CHLORIDE	3GM/100ML	SODIUM CHLORIDE 3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		TRAVENOL LABS	19-022	11-01-83			
SODIUM CHLORIDE	5GM/100ML	SODIUM CHLORIDE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		TRAVENOL LABS	19-022	11-01-83			
SODIUM CHLORIDE	9MG/ML	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	19-217	07-13-84			
SODIUM CHLORIDE	9MG/ML	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	19-218	07-13-84			

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 5-31-85 AND NDAs WITH APPROVED PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
SODIUM CHLORIDE 900MG/100ML	SODIUM CHLORIDE 0.9% IN STERILE PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	19-319 05-17-85		
SODIUM IODIDE, I-123 100 UCI	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PHARM	18-671 05-27-82		
SODIUM IODIDE, I-123 200 UCI	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PHARM	18-671 05-27-82		
SODIUM IODIDE, I-123 400 UCI	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PHARM	18-671 05-27-82		
SODIUM LACTATE 5MEQ/ML	SODIUM LACTATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-947 09-05-84		NS 09-24-86
SODIUM NITROPRUSSIDE 50MG/VIAL	SODIUM NITROPRUSSIDE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-581 07-28-82		
SODIUM PHOSPHATE, DIBASIC; SODIUM PHOSPHATE, MONOBASIC 142MG/ML; 276MG/ML	SODIUM PHOSPHATES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-892 05-10-83		NP 09-24-86
SOMATROPIN 2 IU/VIAL	ASELLACRIN 2 (INJECTABLE; INJECTION)	SERONO LABS	17-726 07-21-83		NS 09-24-86
SORBITOL 3GM/100ML	SORBITOL 3% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-512 05-27-82		
SOYBEAN OIL 10%	SOYACAL 10% (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	18-465 06-29-83		
SOYBEAN OIL 10%	TRAVAMULSION 10% (INJECTABLE; INJECTION)	TRAVENOL LABS	18-660 02-26-82		
SOYBEAN OIL 20%	TRAVAMULSION 20% (INJECTABLE; INJECTION)	TRAVENOL LABS	18-758 02-15-83		

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
SOYBEAN OIL 20%	SOYCAL 20% (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	18-786	06-29-83	18-969	09-24-84	
SOYBEAN OIL 10%	LIPOSYN III 10% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-969	09-24-84	18-970	09-25-84	
SOYBEAN OIL 20%	LIPOSYN III 20% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-970	09-25-84	12-885	11-30-81	
STANZOLOL	WINSTROL (TABLET; ORAL)	WINTHROP LABS/STERL	3704295	11-28-89	1-28	09-24-86	
STREPTOCIN 1GM/VIAL	ZANOSAR (INJECTABLE; INJECTION)	UPJOHN	17-961	05-07-82	05-07-92	NCE	
SUCRALFATE 1GM	CARAFATE (TABLET; ORAL)	MARION LABORATORIES	18-333	10-30-81	03-11-86	3422489	
SUFENTANIL CITRATE EQ 0.05MG BASE/ML	SUFENTA (INJECTABLE; INJECTION)	JANSSEN PHARMA	19-050	05-04-84	12-21-93	3998834	NCE 05-04-94
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	BACTRIM (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-377	07-30-73	06-02-87	RE28636	
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	BACTRIM DS (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-377	03-01-78	06-02-87	RE28636	
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	BACTRIM (SUSPENSION; ORAL)	HOFFMANN-LA ROCHE	17-560	04-16-75	06-02-87	RE28636	I-21 09-24-86
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	BACTRIM PEDIATRIC (SUSPENSION; ORAL)	HOFFMANN-LA ROCHE	17-560	12-10-79	06-02-87	RE28636	I-21 09-24-86
SULFAMETHOXAZOLE; TRIMETHOPRIM 80MG/ML; 16MG/ML	BACTRIM (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	18-374	06-23-81	12-29-87	RE28636	
					06-02-87	3551564	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM (TABLET; ORAL)	DRUMMER/PHOENIX	18-598 05-19-82		
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH (TABLET; ORAL)	DRUMMER/PHOENIX	18-598 05-19-82		
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SULFATRIM PEDIATRIC (SUSPENSION; ORAL)	NATL PHARM MFG/BARRE	18-615 01-07-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SULFATRIM (SUSPENSION; ORAL)	NATL PHARM MFG/BARRE	18-615 01-07-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SMZ-TMP (SUSPENSION; ORAL)	BIOCRAFT LABS	18-812 01-28-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SMZ-TMP PEDIATRIC (SUSPENSION; ORAL)	BIOCRAFT LABS	18-812 06-10-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM (TABLET; ORAL)	DANBURY PHARMACAL	18-852 05-09-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH (TABLET; ORAL)	DANBURY PHARMACAL	18-854 05-09-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	SULFAMETHOXAZOLE & TRIMETHOPRIM (TABLET; ORAL)	HEATHER DRUG	18-946 08-10-84		
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	SULFAMETHOXAZOLE & TRIMETHOPRIM (TABLET; ORAL)	HEATHER DRUG	18-946 08-10-84		
SULFASALAZINE 500MG	AZULFIDINE (TABLET, ENTERIC COATED; ORAL)	PHARMACIA/PHARMACIA	07-073 04-06-83		NDF 09-24-86

ACTIVE INGREDIENT(S)
STRENGTH(S)

TRADE NAME
(DOSAGE FORM; ROUTE)

APPLICANT NAME

NDA NO.
APPROVAL DATE

PATENT NO.
EXP. DATE

EXCLUSIVITY
EXP. DATE

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 5-31-85 AND NDAs WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

SULFASALAZINE 500MG SULINDAC 150MG SULINDAC 200MG SUTILAINS 82,000 UNITS/GM TECHNETIUM, TC-99M SODIUM PERTECHNETATE GENERATOR 0.22-2.22Ci/GENERATOR N/A TECHNETIUM, TC-99M, ALBUMIN COLLOID KIT N/A TECHNETIUM, TC-99M, DISOFENIN KIT TECHNETIUM, TC-99M, GLUCEPATE KIT N/A TECHNETIUM, TC-99M, MEDRONATE N/A TECHNETIUM, TC-99M, MEDRONATE N/A TECHNETIUM, TC-99M, SUCCIMER KIT N/A MPI DMSA KIDNEY REAGENT (INJECTABLE; INJECTION) AMERSCAN (INJECTABLE; INJECTION) OSTEO-LITE (INJECTABLE; INJECTION) TECHNISCAN GLUCEPATE (INJECTABLE; INJECTION) HEPATOLITE (INJECTABLE; INJECTION) MICROLITE (INJECTABLE; INJECTION) MINITEC (SOLUTION; INTRAVENOUS, ORAL) TRAVASE (OINTMENT; TOPICAL) CLINORIL (TABLET; ORAL) CLINORIL (TABLET; ORAL) SULFASALAZINE (TABLET, ENTERIC COATED; ORAL) BOLAR PHARMACEUTICAL 88-052 05-24-83 MS&D/MERCK 17-911 09-27-78 3654349 04-04-89 3725548 04-03-90 3725548 04-03-90 3654349 04-03-90 3654349 04-04-89 3725548 04-03-90 3409719 11-05-85 ER SQUIBB AND SONS 17-339 06-03-74 MED DIAG/NE NUCLEAR 18-263 03-25-83 MED DIAG/NE NUCLEAR 18-467 03-16-82 MS&D/MERCK 18-272 01-27-82 MED DIAG/NE NUCLEAR 17-972 12-16-77 AMERSHAM/RADIOCHEM 18-335 08-05-82 17-944 05-18-82 MEDI-PHYSICS 17-944 05-18-82 4208398 06-17-97 4233285 11-11-97 NP 09-24-86 NP 09-24-86 I-31 09-24-86 NDF 09-24-86	TECHNETIUM, TC-99M, SUCCIMER KIT TECHNETIUM, TC-99M, MEDRONATE TECHNETIUM, TC-99M, MEDRONATE TECHNETIUM, TC-99M, GLUCEPATE KIT TECHNETIUM, TC-99M, DISOFENIN KIT TECHNETIUM, TC-99M, ALBUMIN COLLOID KIT TECHNETIUM, TC-99M SODIUM PERTECHNETATE GENERATOR 0.22-2.22Ci/GENERATOR N/A TECHNETIUM, TC-99M, ALBUMIN COLLOID KIT N/A TECHNETIUM, TC-99M, GLUCEPATE KIT N/A TECHNETIUM, TC-99M, MEDRONATE N/A TECHNETIUM, TC-99M, MEDRONATE N/A MPI DMSA KIDNEY REAGENT (INJECTABLE; INJECTION) AMERSCAN (INJECTABLE; INJECTION) OSTEO-LITE (INJECTABLE; INJECTION) TECHNISCAN GLUCEPATE (INJECTABLE; INJECTION) HEPATOLITE (INJECTABLE; INJECTION) MICROLITE (INJECTABLE; INJECTION) MINITEC (SOLUTION; INTRAVENOUS, ORAL) TRAVASE (OINTMENT; TOPICAL) CLINORIL (TABLET; ORAL) CLINORIL (TABLET; ORAL) SULFASALAZINE (TABLET, ENTERIC COATED; ORAL) BOLAR PHARMACEUTICAL 88-052 05-24-83 MS&D/MERCK 17-911 09-27-78 3654349 04-04-89 3725548 04-03-90 3725548 04-03-90 3654349 04-04-89 3725548 04-03-90 3409719 11-05-85 ER SQUIBB AND SONS 17-339 06-03-74 MED DIAG/NE NUCLEAR 18-263 03-25-83 MED DIAG/NE NUCLEAR 18-467 03-16-82 MS&D/MERCK 18-272 01-27-82 MED DIAG/NE NUCLEAR 17-972 12-16-77 AMERSHAM/RADIOCHEM 18-335 08-05-82 17-944 05-18-82 MEDI-PHYSICS 17-944 05-18-82 4208398 06-17-97 4233285 11-11-97 NP 09-24-86 NP 09-24-86 I-31 09-24-86 NDF 09-24-86
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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
TERBUTALINE SULFATE 0.2MG/INH	BRETHAIRE (AEROSOL; INHALATION)	GEIGY/CIBA-GEIGY	18-762 08-17-84	3937838 02-10-93 4011258 03-08-94	NDF 09-24-86
TERBUTALINE SULFATE 0.2MG/INH	BRICANYL (AEROSOL; INHALATION)	MERRELL DOW/DOW CHEM	18-000 03-19-85	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 1MG/ML	BRICANYL (INJECTABLE; INJECTION)	MERRELL DOW/DOW CHEM	17-466 03-25-74	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 2.5MG	BRICANYL (TABLET; ORAL)	MERRELL DOW/DOW CHEM	17-618 04-22-75	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 5MG	BRICANYL (TABLET; ORAL)	MERRELL DOW/DOW CHEM	17-618 04-22-75	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 2.5MG	BRETHINE (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-849 05-17-76	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 5MG	BRETHINE (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-849 05-17-76	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 1MG/ML	BRETHINE (INJECTABLE; INJECTION)	GEIGY/CIBA-GEIGY	18-571 11-30-81	3937838 02-10-93 4011258 03-08-94	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM: ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
TERFENADINE	60MG	SELDANE	(TABLET: ORAL)	MERRELL DOW/DOW CHEM	18-949	05-08-85	3806526	04-23-91	NCE 05-08-90
THALLOUS CHLORIDE, TL-201	2MCI/ML	THALLOUS CHLORIDE TL 201	(INJECTABLE: INJECTION)	MEDI-PHYSICS	18-110	02-01-82			NS 09-24-86
THALLOUS CHLORIDE, TL-201	1MCI/ML	THALLOUS CHLORIDE TL 201	(INJECTABLE: INJECTION)	AMERSHAM/RADIOCHEM	18-548	12-30-82			
TIMOLOL MALEATE	5MG	BLOCADREN	(TABLET: ORAL)	MS&D/MERCK	18-017	11-25-81	3655663	04-11-89	
TIMOLOL MALEATE	10MG	BLOCADREN	(TABLET: ORAL)	MS&D/MERCK	18-017	11-25-81	3655663	04-11-89	
TIMOLOL MALEATE	20MG	BLOCADREN	(TABLET: ORAL)	MS&D/MERCK	18-017	11-25-81	3655663	04-11-89	
TIMOLOL MALEATE	EQ 0.25% BASE	TIMOLOL	(SOLUTION: OPHTHALMIC)	MS&D/MERCK	18-086	08-17-78	4195085	03-25-97	
TIMOLOL MALEATE	EQ 0.5% BASE	TIMOLOL	(SOLUTION: OPHTHALMIC)	MS&D/MERCK	18-086	08-17-78	4195085	03-25-97	
TONOCARD		(TABLET: ORAL)		MS&D/MERCK	18-257	11-09-84	4218477	08-19-97	NCE 11-09-89
TOCAINIDE HYDROCHLORIDE	400MG						4237068	12-02-97	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
TOCAINIDE HYDROCHLORIDE 600MG	TONOCARD (TABLET; ORAL)	MS&D/MERCK	18-257 11-09-84	4218477 08-19-97 4237068 12-02-97	NCE 11-09-89
TOLAZAMIDE 100MG	TOLAZAMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-894 11-02-84		
TOLAZAMIDE 250MG	TOLAZAMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-894 11-02-84		
TOLAZAMIDE 500MG	TOLAZAMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-894 11-02-84		
TOLAZOLINE HYDROCHLORIDE 25MG/ML	PRISCOLINE (INJECTABLE; INJECTION)	CIBA/CIBA-GEIGY	06-403 02-22-85		
TOLMETIN SODIUM EQ 200MG BASE	TOLECTIN (TABLET; ORAL)	MCNEIL LABORATORIES	17-628 03-24-76	3752826 08-14-90	
TOLMETIN SODIUM EQ 400MG BASE	TOLECTIN DS (CAPSULE; ORAL)	MCNEIL LABORATORIES	18-084 10-30-79	3752826 08-14-90	
TRAZODONE HYDROCHLORIDE 150MG	DESYREL (TABLET; ORAL)	MEAD JOHNSON/B-M	18-207 03-25-85		
TRETINOIN 0.05%	RETIN-A (SOLUTION; TOPICAL)	ORTHO PHARMACEUTICAL	16-921 10-20-71	3729568 04-24-90	
TRETINOIN 0.1%	RETIN-A (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-340 01-26-73	3729568 04-24-90 3906108 09-16-92	
TRETINOIN 0.05%	RETIN-A (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-522 07-19-74	3729568 04-24-90 3906108 09-16-92	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
TRIAMCINOLONE ACETONIDE	0.25MG/INH	AZMACORT (AEROSOL; INHALATION)		WILLIAM H RORER	18-117	04-23-83	08-05-92 3927806	09-24-86 NDF	
RETINOLIN	0.025%	RETIN-A (GEL; TOPICAL)		ORTHO PHARMACEUTICAL	17-579	04-18-75	04-24-90 4247547 01-27-98	09-24-86 NCE	
RETINOLIN	0.01%	RETIN-A (GEL; TOPICAL)		ORTHO PHARMACEUTICAL	17-955	10-05-78	04-24-90 4247547 01-27-98	09-24-86 NCE	
TRIAZOLAM	0.125MG	HALCION (TABLET; ORAL)		UPJOHN	17-892	04-26-85	09-14-93 3987052	11-15-92 NCE	
TRIAZOLAM	0.25MG	HALCION (TABLET; ORAL)		UPJOHN	17-892	11-15-82	09-14-93 3987052	11-15-92 NCE	
TRIAZOLAM	0.5MG	HALCION (TABLET; ORAL)		UPJOHN	17-892	11-15-82	09-14-93 3987052	11-15-92 NCE	
TRILOSTANE	30MG	MODASTANE (CAPSULE; ORAL)		WINTHROP LABS/STERL	18-719	12-21-84		12-21-89 NCE	
TRILOSTANE	60MG	MODASTANE (CAPSULE; ORAL)		WINTHROP LABS/STERL	18-719	12-21-84		12-21-89 NCE	
TRIMETHOPRIM	200MG	PROLOPRIM (TABLET; ORAL)		BURROUGHS WELLCOME	17-943	07-14-82		09-24-86 NS	
TRIMETHOPRIM	200MG	TRIMPEX 200 (TABLET; ORAL)		HOFFMANN-LA ROCHE	17-952	11-09-82		09-24-86 NS	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 5-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
TRIMETHOPRIM 100MG	TRIMETHOPRIM (TABLET; ORAL)	BIOCRAFT LABS	18-679 07-30-82		
TRIMIPRAMINE MALEATE EQ 100MG BASE	SURMONTIL (CAPSULE; ORAL)	IVES LABS/AMHO	16-792 09-15-82		NS 09-24-86
VECURONIUM BROMIDE 10MG/VIAL	NORCURON (NC-45) (INJECTABLE; INJECTION)	ORGANON/AKZONA	18-776 04-30-84	3553212 01-05-88 4237126 12-02-97 4297351 10-27-98	NCE 04-30-94
VERAPAMIL HYDROCHLORIDE 80MG	ISOPTIN (TABLET; ORAL)	KNOLL PHARMACEUTICAL	18-593 03-08-82		NR 09-24-86
VERAPAMIL HYDROCHLORIDE 120MG	ISOPTIN (TABLET; ORAL)	KNOLL PHARMACEUTICAL	18-593 03-08-82		NR 09-24-86
VERAPAMIL HYDROCHLORIDE 80MG	CALAN (TABLET; ORAL)	SEARLE/SEARLE PHARMS	18-817 09-10-84		NR 09-24-86
VERAPAMIL HYDROCHLORIDE 120MG	CALAN (TABLET; ORAL)	SEARLE/SEARLE PHARMS	18-817 09-10-84		NR 09-24-86
VERAPAMIL HYDROCHLORIDE 2.5MG/ML	CALAN (INJECTABLE; INJECTION)	SEARLE PHARMS	18-925 03-30-84		
VERAPAMIL HYDROCHLORIDE 2.5MG/ML	CALAN (INJECTABLE; INJECTION)	SEARLE PHARMS	19-038 03-30-84		
WATER FOR INJECTION, STERILE 100%	STERILE WATER FOR INJECTION IN PLASTIC CONTAINER (LIQUID; N/A)	TRAVENOL LABS	18-595 01-17-83		
WATER FOR INJECTION, STERILE 100%	STERILE WATER IN PLASTIC CONTAINER (LIQUID; N/A)	TRAVENOL LABS	18-632 06-30-82		



NCE
10-01-92
NCE
10-01-92

EXCLUSIVITY
EXP. DATE

PATENT NO.
EXP. DATE

NDA NO.
APPROVAL DATE

APPLICANT NAME

TRADE NAME
(DOSAGE FORM, ROUTE)

ACTIVE INGREDIENT(S)
STRENGTH(S)

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 5-31-85 AND NDAs WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

WATER FOR INJECTION, STERILE	100%	STERILE WATER IN PLASTIC CONTAINER	ABBOTT LABORATORIES	18-801	10-27-82
WATER FOR INJECTION, STERILE	100%	BACTERIOSTATIC WATER IN PLASTIC CONTAINER	ABBOTT LABORATORIES	18-802	10-27-82
WATER FOR INJECTION, STERILE	100%	STERILE WATER FOR INJECTION IN PLASTIC CONTAINER	AM HCGAM/AM HOSP	19-077	03-02-84
XENON, XE-127	5MCI/VIAL	XENON XE 127	MALLINCKRODT	18-536	10-01-82
XENON, XE-127	10MCI/VIAL	XENON XE 127	MALLINCKRODT	18-536	10-01-82
XENON, XE-133	10MCI/VIAL	XENON XE 133	MALLINCKRODT	18-327	03-09-82
XENON, XE-133	10MCI/VIAL	XENON XE 133	MALLINCKRODT	18-327	03-09-82
XENON, XE-133	20MCI/VIAL	XENON XE 133	MALLINCKRODT	18-327	03-09-82

REFERENCE
DOES NOT CONSTITUTE